*Comprehensive Accreditation Manual for Behavioral Health Care*
*2000 Supplement*

**Joint Commission on Accreditation of Healthcare Organizations**
**Opioid Treatment Program Accreditation**

***Note:*** *These methadone/levo-alpha-acetyl-methadol (LAAM) standards are to be used only in the survey of the Methadone/LAAM Treatment Program Accreditation Project that is being conducted through a contract with the Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), Office of Pharmacologic and Alternative Therapies. This project has been approved by the Office of Management and Budget (OMB 0930-0194) which expires on November 30, 2001. Other methadone/LAAM organizations not in the program will continue to be surveyed with the appropriate existing standards in the* CAMBHC.

Public reporting burden for the Opioid Treatment Program Accreditation is estimated as follows:
1) An average of 90 hours per treatment program to review these accreditation standards and assess any needed modification to current program practice;
2) An average of two hours to complete the accreditation application;
3) An average of 30 minutes to complete the survey feedback questionnaire; and
4) An average of three hours to complete the quality improvement plan.
These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing burden, to SAMHSA Reports Clearance Officer, Paperwork Reduction Project (OMB 0930-0194) Room 16-105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a current valid OMB control number. This publication was prepared under contract no. 270987043 from Abuse and SAMHSA. Mike Bacon, MS, served as the government project officer.

***Note:*** *The additional requirements for methadone/LAAM treatment programs (those sections that appear underlined below) are part of the federal program and in the public domain, except for the quoted passages from the copyrighted sources. Only those portions in the public domain may be reproduced or copied without permission from CSAT, with appropriate citation of the source. All other standards, intent statements, examples of implementation, and scoring questions are copyrighted by the Joint Commission and may not be reproduced without the express written permission of the Joint Commission.*

***Rights, Responsibilities, and Ethics (RI)***

**RI.1** Using a framework that reflects the interdependence of care and service delivery and organizational ethical issues, the organization addresses the rights of individuals served and ethical issues in the delivery of care and services.

**Intent of RI.1**
Simply listing the rights of individuals served cannot ensure those rights will be respected. This standard focuses on the organization's efforts to reflect concern and respect for the rights of individuals served during all its interactions with those individuals, on increasing staff awareness of the ethical issues surrounding the provision of care and services, on the organization's policies governing such issues, and on the methods available to support ethical decision making.

The organization supports the following rights of individuals served:

# The right to reasonable access to care, regardless of race, religion, gender, sexual orientation, ethnicity, age, or disability;
# The right to personal dignity;
# The right to care that is considerate and respects the personal value and belief systems of individuals served;
# The right to be informed of the organization's rules and regulations concerning the conduct of the individuals served;
# The right to informed participation in decisions regarding care and services;
# The right to participate in treatment planning including children as appropriate to their age, maturity, and clinical condition, and the right of the family of individuals served to participate in such planning;
# The right to individualized treatment, including:
- adequate and humane services regardless of the source(s) of financial support,
- provision of services within the least restrictive environment possible,
- an individualized treatment or program plan,
- periodic review of the treatment or program plan, and
- an adequate number of competent, qualified, and experienced professional clinical staff to supervise and carry out the treatment or program plan;

# The right to participate in the consideration of ethical issues that arise in the provision of care and services, including:
- resolving conflict,
- withholding resuscitative services,
- forgoing or withdrawing life-sustaining treatment, and
- participating in investigational studies or clinical trials;

# The right to personal privacy and confidentiality of information;

# The right to designate a surrogate decision maker if the individual served is incapable of understanding a proposed treatment or procedure or is unable to communicate his or her wishes regarding care; and
# The right of the individual served and the individual's family to be informed of their rights in a language that they understand.

**Additional Requirements for Methadone/LAAM Treatment Programs**

- Programs support patient choice in seeking alternative therapies while providing appropriate guidance in the process. Programs may provide culturally appropriate or popular and non-harmful alternative therapies as indicated (such as providing a space for sweat lodge ceremonies in a rural clinic serving Native Americans, or acupuncture);
- Programs ensure that adolescents are not harassed or exploited by older patients or staff;
- Programs make provisions to provide for respectful and safe treatment of women;
- Patients have a right to a medication schedule (dosing hours/schedule) which is most accommodating and least intrusive and disruptive for most patients;
- Patients have the right to be informed about potential interactions with and adverse reactions to other substances, including those reactions that might result from interactions and adverse reactions to alcohol, other prescribed or over-the-counter pharmacological agents, other medical procedures, and food;
- Patients have the right to review their own record with clinical staff supervision, and to obtain a timely response to the request for copies of the record;
- Patients have the right to input into program policies and services through patient satisfaction surveys; and
- Patients have the right to be informed regarding the financial aspects of treatment, including the consequences of nonpayment of required fees.
- Programs ensure that patients are made aware of the Consumer Bill of Rights and Responsibilities developed by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. (See "Suggested Readings and Other Resources" section for the eight areas of Consumer Rights and Responsibilities. Also, a complete, detailed copy of the Consumer Bill of Rights can be obtained at www.hcqualitycommission.gov.)

***Note:*** *The federal human subject protection standards generally assume that (1) all participation in new interventions is voluntary; (2) confidentiality of patient records and research data is assured; (3) written, informed consent is obtained; (4) the risks/benefits of participation are explained to participants; (5) participation does not jeopardize ongoing treatment; and (6) the research does not impose an undue burden on participants. (The full federal human subject protection standards are published in 45 CFR, Part 46.)*

**Scoring for RI.1**

a. Does the organization address applicable issues listed in the intent?
b. Can staff explain how these issues are addressed?

c. In a methadone/LAAM treatment program, are the additional nine requirements in the intent addressed?

| | | | |
|---|---|---|---|
| **Score 1** | a. Yes | b. Yes | c. Yes |
| **Score 2** | | b. With a few minor exceptions | |
| **Score 3** | a. One issue is not addressed | b. Not consistently | c. One issue is not addressed |
| **Score 4** | | b. Rarely | |
| **Score 5** | a. No | b. No | c. No |

**RI.1.2.2** Informed consent is obtained from each individual served.

**Intent of RI.1.2.2**

Informed consent is a process. Individuals are given a clear, concise explanation of

# their condition;
# proposed interventions, treatment, or medications;
# the potential benefits, risks, and side effects of proposed interventions, treatment, or medications;
# problems related to recovery;
# the likelihood of success;
# any significant alternative medications, treatments, or interventions; and
# the individual's right, to the extent permitted by law, to refuse medications, treatments, or interventions.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Informed consent should be obtained regarding prescribed pharmacotherapy from each patient before dosing begins;

- Patients are informed, at admission, of the following:
  - 1. The natural history of opioid addiction is altered by time and history;
  - 2. The goal of methadone/LAAM medication therapy is stabilization of functioning; and
  - 3. At periodic intervals, in full consultation with the patient, the provider will discuss present level of functioning, course of treatment, and future goals. These discussions are in no way intended to place an unfair burden or pressure on the patient to withdraw from or maintain the patient on the medication unless medically indicated.
- Patients are informed at admission about state-specific requirements and program policies and procedures regarding the report of suspected child abuse and neglect as well as other forms of abuse such as violence against women (Refer to PE.1.18 through PE.1.18.1.3 for specific assessment requirements regarding abuse and neglect.);

- Patients are informed about the natural progression of their disease including statistics relating to success after withdrawal from methadone;
- Informed consent is obtained when "emancipated minors" are admitted to the program. The parent, legal guardian, or responsible adult must complete and sign consent form FDA 2635 "Consent to Methadone Treatment" (also see CC.2.1 regarding admission criteria);
- Informed consent is obtained from pregnant patients referred for prenatal care to ensure reciprocity in the exchange of pertinent clinical information regarding compliance with the recommended course of medical care;
- If a pregnant patient refuses direct prenatal services or appropriate referral for such care, the treating physician may use informed consent procedures to have the patient formally acknowledge in writing that these services were offered but refused;
- Informed consent policies are established and implemented to ensure appropriate follow-up primary care of new mothers and well baby care for their infants; and
- A patient's written acknowledgment is obtained to provide evidence that the patient received a copy of his/her rights and responsibilities and the rules and regulations governing patient conduct and responsibilities and that these rights and responsibilities were discussed with the patient.

**Scoring for RI.1.2.2**

a. Does the organization obtain the informed consent of each individual served?
b. In a methadone/LAAM treatment program, does the organization address and obtain informed consent for the nine areas addressed above, when appropriate?

| | | |
|---|---|---|
| **Score 1** | a. Yes | b. Yes |
| **Score 3** | | b. Not consistently |
| **Score 5** | a. No | b. No |

**RI.1.2.5** Individuals served are involved in resolving conflicts in care decisions.

**Intent of RI.1.2.5**

The organization has defined a process for reviewing and assessing the needs, requests, and complaints about care communicated by individuals served and families. All populations served have access to such a process. In addition, individuals served have the right to request the opinion of a consultant at their expense or to request an in-house review of the individual treatment plan, as outlined in organization procedures.

The conflict-resolution process is developed by clinical and other staff and is appropriately approved. The organization also defines the final authority for addressing admission, treatment, and discharge issues. When individuals refuse treatment, they are given full information about the organization's responsibility to seek appropriate legal alternatives or orders of involuntary treatment, or, in accordance with professional standards, to terminate the relationship between the individual served and the provider upon reasonable notice.

**Additional Requirements for Methadone/LAAM Treatment Programs**

The conflict resolution process should also require that

- patients have the right to receive a decision in writing with the reasoning articulated;
- patients have the right to appeal the decision to a final, unbiased source;
- the program makes every attempt, before a patient is discharged, to accommodate the patient's desire to remain in some type of methadone/LAAM therapy at an alternative treatment program;
- involuntary withdrawal is only used as a sanction of last resort that is accomplished in the most humane manner consistent with the safety and well-being of staff, other patients, and the program; and
- the patient's methadone dose not be changed without the patient's knowledge unless the patient signs a document waiving such consent.

**Example of Implementation for RI.1.2.5**

A methadone/LAAM program may use the State Methadone Authority or the State Bureau of Licensing to address appeals that cannot be resolved at the program or organization level.

**Scoring for RI.1.2.5**

a. Has a process been defined and approved for resolving care-related conflicts between either individuals served or the families of individuals served and the organization?

b. In methadone/LAAM treatment programs, does the conflict resolution process address the five additional areas?

| | | |
|---|---|---|
| **Score 1** | a. Yes | b. Yes |
| **Score 3** | | b. Not consistently |
| **Score 5** | a. No | b. No |

**RI.1.8** All individuals served receive a written statement of their rights.

**Intent of RI.1.4 Through RI.1.8**

In addition to the influence of cultural, psychosocial, and spiritual beliefs on the course of care, other issues concerning respect influence care, such as

# privacy and security within the constraints of the treatment plan;
# the individual's and family's right to initiate a complaint or grievance procedure and to have complaints reviewed and, when possible, resolved;
# effective communication in the language of the population group(s) served;
# the right to confidentiality of information;
# the right of visitation by family and significant others, unless clinically contraindicated;
# the right to send and receive mail without hindrance; and
# the right to conduct private telephone conversations.

Full information is given to the individual served on the current and future use of special observation and audiovisual techniques, such as one-way mirrors, tape recorders, television, movies, or photographs.

If therapeutic indications necessitate restrictions on visitors, telephone calls, or other communications, those restrictions are evaluated for therapeutic effectiveness by the clinically responsible staff. Such limitations are determined with the participation of the individual and the individual's family and are fully explained to them. Clinically responsible staff evaluate any restrictions for therapeutic effectiveness at least every three days or at intervals consistent with ongoing care review and the average length of stay in the organization.

All individuals served receive a written statement of their rights in a language they understand while they are receiving treatment within the organization. Individuals who are disoriented or in a state of anxiety at the time of admission are informed of their rights at an appropriate time during treatment. Statements of rights are available to individuals served throughout treatment.

**Additional Requirements for Methadone/LAAM Treatment Programs**

The written statement of patient rights should encompass all areas addressed under RI.1.

**Scoring for RI.1.8**

a. What percentage of individuals served has received a written statement of their rights?
b. In methadone/LAAM treatment programs, what percentage of individuals received a statement of their rights which encompassed the areas addressed under RI.1?

| | | |
|---|---|---|
| **Score 1** | a. 100% | b. 100% |
| **Score 3** | a. 95% to 99% | b. 95% to 99% |
| **Score 5** | a. Less than 95% | b. Less than 95% |

***Assessment (PE)***

**PE.1.5** *An emotional and behavioral assessment of each individual is completed and entered in the clinical record. The assessment includes at least a history of emotional, behavioral, and substance-abuse problems, their co-occurrence or treatment, including*

**PE.1.5.1** use of alcohol and other drugs by the individual or by family members;

**PE.1.5.2** current emotional and behavioral functioning;

**PE.1.5.3** maladaptive or problem behaviors;

**PE.1.5.4** when indicated, a psychiatric evaluation;

**PE.1.5.5** when indicated, a mental status examination appropriate to the individual's age;

**PE.1.5.6** when indicated, a psychological assessment, including intellectual, projective, neuropsychological, and personality testing; and

**PE.1.5.7** when indicated, other functional evaluations of language, self-care, visual-motor, and cognitive functioning.

**Intent of PE.1.5 Through PE.1.5.7**
Assessment of each individual's emotional and behavioral functioning may be conducted by using a variety of assessment tools. It may include evaluations by multiple disciplines and vary according to individuals' ages and disabilities.
Regardless of the technique used, the emotional and behavioral assessment always addresses the individual's history of mental health or behavioral problems and the circumstances surrounding the current admission. Assessment documentation includes integrating the assessment findings by clinicians.

**Additional Requirements for Methadone/LAAM Treatment Programs**

The assessment/evaluation should be conducted within approximately 30 days of initiation of patient treatment.

**Scoring for PE.1.5**

a. Is an emotional/behavioral assessment completed for each individual served and entered in the clinical record?
b. In methadone/LAAM treatment programs, is the emotional/behavioral assessment completed within approximately 30 days of initiation of patient treatment?

| | | |
|---|---|---|
| **Score 1** | a. Yes | b. Yes |
| **Score 2** | a. With a few minor exceptions | b. With a few minor exceptions |
| **Score 3** | a. Not consistently | b. Not consistently |
| **Score 4** | a. Rarely | b. Rarely |
| **Score 5** | a. No | b. No |

**PE.1.12** A physical health assessment, including a medical history and physical examination, is completed within 24 hours after admission to inpatient programs and within one week after admission to residential and therapeutic foster care programs.

**Note:** *This standard applies to inpatient programs, residential programs., therapeutic foster care programs, overnight crisis stabilization or other programs that house patients overnight.*

**Intent of PE.1.12**

This assessment is performed by a licensed independent practitioner, who is qualified and competent to do so, within 24 hours of admission to inpatient programs and within one week after admission to residential programs and therapeutic foster care settings. This time frame applies to weekend and holiday admissions as well as to weekdays. Some situations may occur in which medical needs require completion of a physical health assessment within a shorter time frame.

If a comprehensive medical history and physical examination have been completed within 30 days before admission to the organization, a durable, legible copy of this report may be used in the clinical record as the physical health assessment, but any subsequent changes must be recorded at the time of admission. A physical health assessment conducted before admission may be used as an assessment tool in care planning only when

- it includes a medical history and physical examination;
- it was conducted by a competent and qualified licensed independent practitioner within 30 days of the current course of treatment; and
- the individual's condition remains consistent with the results of that examination.

The organization has documentation showing that the information is current. In addition, by accepting such a health assessment, the organization attests to its accuracy, completeness, and relevancy to the current course of treatment. The organization may never abdicate this responsibility to referral sources or other mental health professionals.

**Additional Requirements for Methadone/LAAM Treatment Programs**

A physical health assessment, including a medical history and a physical examination is completed within seven days after admission.

**Scoring for PE.1.12**

a. What percentage of clinical records indicates that physical health assessments were completed within the time frames specified for the setting?

b. In methadone/LAAM treatment programs, what percentage of clinical records indicates that physical health assessments were completed within seven days after admission?

| | | |
|---|---|---|
| **Score 1** | a. 90% to 100% of those reviewed | b. 100% of those reviewed |
| **Score 2** | a. 75% to 89% of those reviewed | b. 95% to 99% of those reviewed |
| **Score 3** | a. 50% to 74% of those reviewed | b. 90% to 94% of those reviewed |
| **Score 4** | a. 25% to 49% of those reviewed | b. 80% to 89% of those reviewed |
| **Score 5** | a. Less than 25% of those reviewed | b. Less than 80% of those reviewed |

**PE.1.12.1** The physical health assessment consists of a medical history and, as indicated, a physical examination.

**Intent of PE.1.12.1**

When a physical health assessment is conducted, it includes a complete medical history. Information gathered includes known diseases and specific physical complaints; previous hospitalizations and operative procedures; medications being taken; family history of illness; physical abuse; infectious and communicable diseases; current and past history of substance abuse, including age of onset, duration, patterns, and consequences of use; and the types of and responses to previous treatment. Physical health questions raised by the medical history are addressed in the current physical examination.

**Additional Requirements for Methadone/LAAM Treatment Programs**

The physical health assessment includes at a minimum:

- Urine drug screens;
- Tuberculosis (TB) skin test; and
- Screening for syphilis.

The physical examination must also focus on clinical signs, complications of addiction (liver problems, multiple traumas) and symptoms of addiction (such as needle marks, constricted or dilated pupils, eroded or perforated nasal septum, and the state of sedation or withdrawal characterized by yawning, restlessness, irritability, chills, perspiration, nausea, or diarrhea).

A medical and family history must be documented. The history should include current information to determine chronic or acute medical conditions, such as diabetes, renal diseases, hepatitis B, C, and delta, HIV exposure, TB, sexually transmitted diseases (STDs), other infectious diseases, sickle-cell trait or anemia, pregnancy (including past history of pregnancy and current involvement in prenatal care), and chronic cardiopulmonary disease.

**Scoring for PE.1.12.1**

a. Do all physical health assessments include a complete medical history, as described in the intent?
b. In methadone/LAAM treatment programs, do all physical health assessments include urine drug screens?
c. In methadone/LAAM treatment programs, do all physical health assessments include TB skin tests?
d. In methadone/LAAM treatment programs, do all physical health assessments include screening for syphilis?
e. In methadone/LAAM treatment programs, do physical examinations focus on clinical signs, complications of addiction, and symptoms of addiction?
f. In methadone/LAAM treatment programs, does the medical and family history include current information to determine chronic or acute medical conditions?

| | | |
|---|---|---|
| **Score 1** | a. Yes | b. Yes |
| **Score 2** | a. With a few minor exceptions | |
| **Score 3** | a. Not consistently | b. Not consistently |

| | | |
|---|---|---|
| **Score 4** | a. Rarely | |
| **Score 5** | a. No | b. No |
| | | |
| **Score 1** | c. Yes | d. Yes |
| **Score 2** | | |
| **Score 3** | c. Not consistently | d. Not consistently |
| **Score 4** | | |
| **Score 5** | c. No | d. No |
| | | |
| **Score 1** | e. Yes | f. Yes |
| **Score 2** | e. With a few minor exceptions | f. With a few minor exceptions |
| **Score 3** | e. Not consistently | f. Not consistently |
| **Score 4** | e. Rarely | f. Rarely |
| **Score 5** | e. No | f. No |

**PE.1.15** Diagnostic testing is performed to determine individuals' health care needs and as part of care.

**PE.1.15.1** When the report of test results requires clinical interpretation, adequate clinical information is supplied with the request for the test.

**Intent of PE.1.15 and PE.1.15.1**
Diagnostic testing includes laboratory and other invasive and noninvasive diagnostic and imaging procedures as well as psychological tests. It also includes appropriate use of laboratory, radiologic, electrodiagnostic, and other tests and imaging technologies integral to the physical, psychological, and social assessment of the individual. A qualified licensed independent practitioner determines which tests, if any, should be performed when the individual enters the program or service. Requests for diagnostic testing include enough information, in writing, to facilitate testing and interpreting results.

**Additional Requirements for Methadone/LAAM Treatment Programs**

The medical laboratory analysis may include:

- Complete Blood Count (CBC);
- Routine chemistry profile and drug screening panel;
- Chest x-ray;
- Screening tests for infectious diseases, HIV and STDs;
- EKG;
- Pap smear;
- Screening test for sickle cell anemia;
- Hepatitis B antigen and surface antibody; and

- Testing for other drugs based on individual medical indicators and community drug use patterns.

Programs conduct an initial urine or other toxicology test as part of the admission process.

All urine and other toxicological specimens are collected in a context that suggests trust and respect while taking reasonable steps to prevent falsification of samples. Reliance on direct observation, one-way mirrors, and video cameras, although necessary for some, is neither necessary nor appropriate for all individuals served.

Urine drug screening (as well as other adequately tested toxicological testing procedures) is used as an aid in monitoring and evaluating a patient's progress in treatment within a context that assesses a variety of outcome measures.

Urine drug-screening tests must be analyzed for opiates, methadone, amphetamines, cocaine, and barbiturates a minimum of eight times per year. Urine testing for other drug use should be determined by community drug use patterns or individual medical indications.

Program staff addresses results of urine screens promptly with patients to facilitate rapid intervention with any drug taking that was disclosed or possible diversion of methadone as evidenced by lack of methadone or its metabolites in the urine.

Treatment programs establish procedures for addressing potentially false positive and false negative urine or other toxicology test results following principles outlined in TIP 1, *State Methadone Guidelines.*

**Scoring for PE.1.15**

a. Do appropriately qualified staff determine which diagnostic tests are performed as part of each individual's assessment and care?
b. What percentage of clinical records indicates that appropriate tests are performed as part of the assessment?
c. In methadone/LAAM treatment programs, what percentage of clinical records indicate that initial urine or other toxicology tests are conducted as part of the admission process?
d. In methadone/LAAM treatment programs, are urine and toxicological specimens collected in a manner that suggests trust and respect, minimizing falsification?
e. In methadone/LAAM treatment programs, is urine drug screening used as an aid to monitor and evaluate a patient's progress in treatment?
f. In methadone/LAAM treatment programs, are urine drug-screening tests analyzed for opiates, methadone, amphetamines, cocaine, and barbiturates a minimum of eight times per year?
g. In methadone/LAAM treatment programs, do program staff address urine results promptly with patients?

h. In methadone/LAAM treatment programs, do programs establish procedures for addressing potentially false positive and false negative urine or toxicology tests?

| | | | |
|---|---|---|---|
| **Score 1** | a. Yes | b.100% of those reviewed | c.100% of those reviewed |
| **Score 2** | | b. 95% to 99% | c. 95% to 99% |
| **Score 3** | | b. 90% to 94% | c. 90% to 94% |
| **Score 4** | | b. 80% to 89% | c. 80% to 89% |
| **Score 5** | a. No | b. Less than 80% | c. Less than 80% |

***Note:*** *The following set of scoring applies to each of the remaining score questions (c-h).*

| | |
|---|---|
| **Score 1** | 100% of those reviewed |
| **Score 2** | 95% to 99% |
| **Score 3** | 90% to 94% |
| **Score 4** | 80% to 89% |
| **Score 5** | Less than 80% |

**PE.1.22** *Assessment or reassessment of individuals receiving treatment for chemical dependency addresses*

**PE.1.22.1** history of alcohol, nicotine, and other drug use, including age of onset, duration, patterns of use, and consequences of use;

**PE.1.22.2** history of physical problems associated with dependence;

**PE.1.22.3** use of alcohol and other drugs by family members;

**PE.1.22.4** religion and spiritual orientation;

**PE.1.22.5** types of previous treatment and responses to that treatment; and

**PE.1.22.6** any history of abuse.

**Intent of PE.1.22 Through PE.1.22.6**

Obtaining and interpreting information about substance abuse is necessary to develop treatment plans. By getting the data/information on the items listed in the standards, the clinician can

- assess the relationship of the physical state of each individual to the dependence;
- assess the nature of the individual's compulsion to use alcohol or other drugs;
- assess the intensity of the individual's mental preoccupation with using alcohol or drugs;
- distinguish between alcohol-related and other drug-related symptoms and other preexisting physical problems or pathologic behaviors; and
- establish a predictive value for success of treatment.

Factors assessed and considered in providing services to the individual served include

# obtaining a history of mental, emotional, and behavioral problems; their co-occurrences with substance use problems; and their treatment.
# identifying the physical, emotional, behavioral, and social functioning of the individual before the onset of chemical dependency.
# evaluating the effects that chemical dependency has had on each individual's physical, emotional, and social well-being.
# evaluating patterns of use, for example, continuous, episodic, or binge use.
# identifying consequences of use, for example, legal problems, divorce, loss of friends, job-related incidents, financial difficulties, blackouts, memory impairment.
# assessing the history of physical problems associated with chemical dependency to help substantiate the diagnosis, to anticipate potential medical problems related to chemical withdrawal management, to identify the individual's level of function, and to help the individual who is minimizing the physical consequences of dependence.
# assessing information about the use of alcohol or other drugs by the family to enhance understanding of the individual's behavioral dynamics and help determine the potential for extended family support, as well as the impact of family circumstances on treatment.
# assessing each individual's spiritual orientation, which may relate to the dependency in terms of how the individual views himself/herself as an individual of value and worth. Spiritual orientation is not considered synonymous with an individual's relationship with an organized religion.
# assessing any previous treatment and response to the treatment to see whether the individual responded appropriately to the treatment and if expected outcomes were achieved. If not, what revisions were made, if any?
# assessing whether the individual has experienced a history of abuse (including physical or sexual abuse either as the abuser or the abused) that may affect the individual's ability to address his or her dependence.

## Additional Requirements for Methadone/LAAM Treatment Programs

### Pain Patients

Careful diagnostic distinctions are made between the physical dependence associated with chronic administration of opioids for relief of pain and the disease of opioid addiction. Apparent drug-seeking behaviors, typically associated with the disease of chronic opioid addiction, may occur as a response to inadequately treated or prolonged pain ("pseudo-addiction"). The physical dependence and tolerance to opioids seen in some chronic pain patients is an expected physiological response to methadone/LAAM therapy and does not support a diagnosis of active opioid addiction.

Four of the seven criteria for "Substance Dependence" included in the DSM-IV are useful in differentiating chronic pain patients with opioid dependence problems who are appropriate candidates for methadone/LAAM therapy from those who are not. The relevant criteria are:

- unsuccessful efforts to control use (loss of control);
- large amounts of time spent in activities to obtain or recover from effects; that is, compulsion (except as necessary to obtain pain relief);
- giving up, or reducing important social, occupational, or recreational activities; and
- continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance (DSM-IV, p. 181).

**Note:** *Patients who are dually diagnosed with addiction and a pain disorder may receive treatment in a methadone/LAAM program if such a program provides expertise or is the only source of treatment.*

**Scoring for PE.1.22.1 Through PE.1.22.6**
**Note:** *The following set of guidelines applies to each standard PE.1.22.1 through PE.1.22.6.*

a. What percentage of clinical records indicates that the information specified in the standard is collected during the assessment process for individuals receiving treatment for chemical dependence?
b. Is the scope of the evaluation sufficient to evaluate the areas identified in the standards?
c. In methadone/LAAM treatment programs, are the above four relevant criteria for "substance dependence" (included in the DSM-IV) considered in the assessment process for the purpose of differentiating chronic pain patients with opioid dependence problems who are appropriate candidates for methadone/LAAM therapy from those who are not?

| | | |
|---|---|---|
| **Score 1** | a. 100% of those reviewed | b. Yes |
| **Score 2** | a. 95% to 99% of those reviewed | b. With a few minor exceptions |
| **Score 3** | a. 90% to 94% of those reviewed | b. Not consistently |
| **Score 4** | a. 80% to 89% of those reviewed | b. Rarely |
| **Score 5** | a. Less than 80% of those reviewed | b. No |

| | |
|---|---|
| **Score 1** | c. Yes |
| **Score 2** | c. With a few minor exceptions |
| **Score 3** | c. Not consistently |
| **Score 4** | c. Rarely |
| **Score 5** | c. No |

**PE.1.23** Discharge-planning needs are assessed.

**Intent of PE.1.23**

To facilitate timely, appropriate, and continuous post-discharge care, assessments are conducted to support discharge planning. When indicated, this planning begins when the individual enters the setting. Discharge planning is most effective when related assessment processes are established and consistently used.

**Example of Implementation for PE.1.23**

For a methadone/LAAM treatment program, discharge planning does not necessarily occur when the patient enters treatment. It should occur at an appropriate time based on the individual's expected date of discharge.

**Scoring for PE.1.23**
a. Does the organization have a process for assessing discharge-planning needs?
b. Are discharge-planning needs assessed?

**Score 1** a. Yes
b. Yes
**Score 2** b. With a few minor exceptions
**Score 3** b. Not consistently
**Score 4** b. Rarely
**Score 5** a. No
b. No

**PE.3** Each individual is reassessed at regularly specified times determined by the course of treatment.

**PE.3.1** Each individual is reassessed to evaluate his or her response to treatment.

**PE.3.2** Individuals are reassessed when significant changes occur in their condition.

**PE.3.3** Individuals are reassessed when significant changes occur in their diagnosis.

**Intent of PE.3 Through PE.3.3**
To ensure that care decisions continue to be appropriate, each individual's status is periodically reviewed. This review process is ongoing throughout the individual's contact with the organization and is triggered at key decision points as well as at intervals specified by the organization. The content of the review process and the interval between assessments is defined in organization planning documents.

Reassessment of individuals receiving treatment for alcoholism or other drug dependence considers the impact of major life changes on their treatment. The reassessment addresses the long-term and short-term effectiveness of specific services provided to meet the individual's needs.

Informed decision making is based on regular reassessment using mutually agreeable and reliable measures of the individual's choices, goals, strengths, symptoms, and behavioral patterns.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Assessment updates should be conducted quarterly for the first year of continuous treatment and semiannually for subsequent years.

**Scoring for PE.3 Through PE.3.3**
**Note:** *All of these standards PE.3 through PE.3.3 are scored together.*

a. What percentage of applicable clinical records indicates that individuals are reassessed at one of the decision points defined in the standards?
b. Is the scope of reassessments sufficient for the purposes described in the standards?
c. In methadone/LAAM treatment programs, what percentage of records indicates that assessment updates are conducted quarterly for the first year of continuous treatment and semiannually for subsequent years?

| | | |
|---|---|---|
| **Score 1** | a. 90% to 100% of those reviewed | b. Yes |
| **Score 2** | a. 75% to 89% of those reviewed | b. With a few minor exceptions |
| **Score 3** | a. 50% to 74% of those reviewed | b. Not consistently |
| **Score 4** | a. 25% to 49% of those reviewed | b. Rarely |
| **Score 5** | a. Less than 25% of those reviewed | b. No |

| | |
|---|---|
| **Score 1** | c. 90% to 100% of those reviewed |
| **Score 2** | c. 75% to 89% of those reviewed |
| **Score 3** | c. 50% to 74% of those reviewed |
| **Score 4** | c. 25% to 49% of those reviewed |
| **Score 5** | c. Less than 25% of those reviewed |

***Care (TX)***

**TX.1** Treatment planning identifies care and services appropriate to the individual's specific needs and the severity of condition, impairment, or disability.

**Intent of TX.1**
Delivering care and services effectively and efficiently requires planning. The treatment-planning process is designed to identify and incorporate each individual's unique needs, expectations, and characteristics into an individualized and appropriate plan. The nature of the individual's needs and condition, as determined through assessment, is a primary consideration during the planning process.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Concurrent abuse of other drugs is managed.

**Scoring for TX.1**

a. Is treatment planning individualized and responsive to individual needs?
b. In methadone/LAAM treatment programs, is concurrent abuse of other drugs managed?

| | | |
|---|---|---|
| **Score 1** | a. 100% of the time | b. Yes |
| **Score 2** | a. 90% to 99% of the time | |
| **Score 3** | a. 75% to 89% of the time | |
| **Score 4** | a. 50% to 74% of the time | |
| **Score 5** | a. Less than 50% of the time | b. No |

**TX.1.3** Qualified and competent individuals plan and provide care and services specific to the individual's needs and, as appropriate to the care and services given, in a collaborative and interdisciplinary manner.

**Intent of TX.1.3**

When appropriate to the services provided, collaborative and interdisciplinary care planning and delivery facilitate responsiveness to individual needs, achievement of care goals, and optimal outcomes. Care and services provided are always appropriate to individuals' identified needs. The mix of disciplines involved in care depends on the services provided, and the intensity of collaboration varies according to each individual's needs. Services are provided by qualified rehabilitation professionals whom the organization has determined to be competent by education, licensure, registration, certification, training, or experience.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Patients with both a chronic pain disorder and active opioid addiction are managed by multidisciplinary teams that include addiction medicine specialists and pain medicine specialists, as appropriate.

**Scoring for TX.1.3**

a. Are care-planning and delivery processes throughout the organization interdisciplinary and collaborative, when appropriate, to the services provided?
b. Are individuals involved in care planning and delivery appropriately qualified?
c. In methadone/LAAM treatment programs, are patients with both a chronic pain disorder and active opioid addiction managed by multidisciplinary teams that include addiction medicine specialists and pain medicine specialists, as appropriate?

| | | |
|---|---|---|
| **Score 1** | a. Yes | b. Yes |
| **Score 2** | a. With a few minor exceptions | b. With a few minor exceptions |

| | | |
|---|---|---|
| **Score 3** | a. Not consistently | b. Not consistently |
| **Score 4** | a. Rarely | b. Rarely |
| **Score 5** | a. No | b. No |

| | |
|---|---|
| **Score 1** | c. Yes |
| **Score 2** | c. With a few minor exceptions |
| **Score 3** | c. Not consistently |
| **Score 4** | c. Rarely |
| **Score 5** | c. No |

**TX.1.10** Goals are periodically evaluated and, when necessary, revised based on reassessment of the individual's current clinical problems, needs, and responses to treatment.

**Intent of TX.1.10**
This evaluation is conducted when major clinical changes occur and at specified regular intervals related to the individual's treatment. The treatment-planning process is designed to respond to individuals' current needs and clinical status over time, providing continuous, appropriate care. At regular intervals and in response to specific events, the plan is updated to reflect any changes in the individual's needs and responses to treatment.

Written policies and procedures specify the time frames and criteria for reviewing and updating treatment plans. During plan revision, problem statements, specific goals, treatment objectives, and treatment services are updated as necessary.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Treatment plan updates should be conducted quarterly for the first year of continuous treatment and semiannually for subsequent years.

**Scoring for TX.1.10**
a. Are treatment plans re-evaluated as identified in the intent?
b. Are they revised to reflect current individual needs?
c. In methadone/LAAM treatment programs, are treatment plan updates conducted quarterly for the first year of continuous treatment and semiannually for subsequent years?

| | | |
|---|---|---|
| **Score 1** | a. 100% of the time | b. Yes |
| **Score 2** | a. 90% to 99% of the time | b. With a few minor exceptions |
| **Score 3** | a. 75% to 89% of the time | b. Not consistently |
| **Score 4** | a. 50% to 74% of the time | b. Rarely |
| **Score 5** | a. Less than 50% of the time | b. No |

| | |
|---|---|
| **Score 1** | c. 90% to 100% of the time |

| | |
|---|---|
| **Score 2** | c. 75% to 89% of the time |
| **Score 3** | c. 50% to 74% of the time |
| **Score 4** | c. 25% to 49% of the time |
| **Score 5** | c. Less than 25% of the time |

**TX.2.2** The preparation, dispensing, and storage of medications adhere to law, regulation, licensure, and professional standards of practice.

**Intent of TX.2.2**
When the organization prepares, dispenses, and stores medications, it demonstrates an understanding of, and compliance with, the applicable laws, regulations, professional licensure, and practice standards governing the provision of pharmacy services and use of medications.

**Additional Requirements for Methadone/LAAM Treatment Programs**

**General Dosage**

The dose of methadone/LAAM maintenance medication is individually determined on the basis of good clinical judgment after examination of the patient by a physician or other professional practitioner with prescribing privileges who is knowledgeable about and experienced in addiction medicine including methadone/LAAM therapy.

The program should have the capability of obtaining medication blood levels when clinically indicated.

Doses of methadone and LAAM or other approved medications are adjusted as needed if a program switches from one generic formulation to another and differences in effective dose cause clinically relevant complaints.

**Example of Implementation for TX.2.2**

A methadone/LAAM program obtains medication blood levels at the following times:
- When a patient is overly sedated with only methadone in the blood stream, and
- If a patient is receiving more than 100 mg but continues to use illicit opiates.

**Scoring for TX.2.2**
a. Does the organization adhere to all applicable law, regulation, licensure, and professional standards of practice for preparation, dispensing, and storage of medications?
b. In methadone/LAAM treatment programs, is the dose of methadone/LAAM maintenance medication individually determined by a practitioner with prescribing privileges who is knowledgeable about and experienced in addiction medicine?

c. In methadone/LAAM treatment programs, are medication blood levels obtained when clinically indicated?
d. In methadone/LAAM treatment programs, are doses of medication adjusted as needed if the program switches from one generic formulation to another and differences in effective dose cause clinically relevant complaints?

**Score 1** a. Yes
**Score 5** a. No

***Note:*** *The following set of scoring applies to each of the remaining score questions (b-d).*

**Score 1** Yes
**Score 2** With a few minor exceptions
**Score 3** Not consistently
**Score 4** Rarely
**Score 5** No

**TX.2.2.1** Medications are appropriately controlled during preparation and dispensing.

**TX.2.2.2** If the organization prepares, dispenses, or stores medications, a medication-dose system is followed.

**TX.2.2.3** A pharmacist reviews all prescriptions ordered.

**Intent of TX.2.2.1 Through TX.2.2.3**

Appropriate staff develop and maintain systems for controlling all medications stored at the organization, whether prepared by the organization's pharmacy service or obtained elsewhere by the individual. To ensure the safe and accurate dispensing of medications,

# a pharmacist reviews each prescription or order prior to dispensing (with the possible exceptions of emergency orders when time may not permit, and in situations in which a licensed independent practitioner with appropriate clinical privileges controls prescription, preparation, and administration);
# the pharmacist contacts the prescriber or orderer if questions arise;
# medications dispensed to both inpatients and outpatients are appropriately and safely labeled using a standardized method; and
# medications are dispensed in the most ready-to-administer form possible to minimize opportunities for error.

See also TX.2.2.5 which addresses providing medications when the pharmacy service is closed or access to medications is limited.

**Additional Requirements for Methadone/LAAM Treatment Programs**

A procedure is established for calibrating medication dispensing instruments consistent with manufacturers' recommendations to ensure accurate patient dosing and substance tracking.

**Diversion Control**

Methadone/LAAM treatment programs have a diversion control plan. The diversion control plan demonstrates accountability and efficient use of personnel and other resources to achieve the highest quality of patient care while reducing possibilities for diversion of controlled substances from legitimate treatment to illicit use.
The diversion control plan should include:

- a mechanism for continuous monitoring of clinical and administrative activities, to reduce the risk of medication diversion;
- a mechanism for problem identification and correction, and for prevention of related diversion problems; and
- a mechanism for demonstrating accountability to patients and the community.

**Example of Implementation for TX.2.2.1**

A methadone/LAAM treatment program developed a diversion control plan that addressed both employees and patients. The plan for employees required the following:

- random and unannounced drug screening;
- video camera surveillance in medication area(s);
- employees not take purses or bags into the medication area(s);
- only licensed personnel can be present in the medication area(s) when medications are being dispensed or administered;
- activities in medication area(s) are limited to preparation, administration, and dispensing of medications; and
- take-home medications dispensed by staff are periodically assayed to determine if the dosage is appropriate.

The plan for patients requires the following:

- only one patient at a time at the medication window;
- call-back program for patients to bring back their take-home medications to check how many remaining doses are left and to check the dosages;
- surveillance in the parking lot and surrounding area;
- no loitering by patients around the building and surrounding area;
- the assignment of a staff member to act as a community liaison to establish a relationship with local businesses, community members, and the police department. The community liaison would ask the businesses, community members and police department to report any suspicious or unusual activities in the surrounding area to the methadone/LAAM program.

**Scoring for TX.2.2.1**

a. Are there systems to ensure that all medications are appropriately controlled and accounted for?

b. Are the systems carried out?

c. In methadone/LAAM treatment programs, is a procedure established for calibrating medication dispensing equipment?

d. In methadone/LAAM treatment programs, has a diversion control program been established?

e. In methadone/LAAM treatment programs, does the diversion control plan include a mechanism for continuous monitoring of clinical and administrative activities?

f. In methadone/LAAM treatment programs, does the diversion control plan have a mechanism for problem identification and correction, and for prevention of related diversion problems; and

g. In methadone/LAAM treatment programs, does the diversion control plan have a mechanism for demonstrating accountability to patients and the community?

| | | | | |
|---|---|---|---|---|
| **Score 1** | a. Yes | b. Yes | c. Yes | d. Yes |
| **Score 5** | a. No | b. No | c. No | d. No |

***Note:*** *The following set of scoring applies to each of the remaining score questions (e-g).*

| | |
|---|---|
| **Score 1** | Yes |
| **Score 3** | Not consistently |
| **Score 5** | No |

**TX.2.2.3** A pharmacist reviews all prescriptions or orders.

**Intent of TX.2.2.1 Through TX.2.2.3**

Appropriate staff develop and maintain systems for controlling all medications stored at the organization, whether prepared by the organization's pharmacy service or obtained elsewhere by the individual. To ensure the safe and accurate dispensing of medications,

- a pharmacist reviews each prescription or order prior to dispensing (with the possible exceptions of emergency orders when time may not permit, and in situations in which a licensed independent practitioner with appropriate clinical privileges controls prescription, preparation, and administration);
- the pharmacist contacts the prescriber or orderer if questions arise;
- medications dispensed to both inpatients and outpatients are appropriately and safely labeled using a standardized method; and
- medications are dispensed in the most ready-to-administer form possible to minimize opportunities for error.

See also TX.2.2.5 which addresses providing medications when the pharmacy service is closed or access to medications is limited.

**Example of Implementation for TX.2.2.3**

Physicians may order, dispense, and administer methadone/LAAM if they have the appropriate clinical privileges to do so. In this instance, a pharmacist would not be required to review each order before the medication is dispensed.

**Scoring for TX.2.2.3**

a. Are all prescriptions or orders reviewed by a pharmacist, as described in the intent?
b. Are prescriptions or orders verified as described in the intent?

**Score 1** a. Yes
b. Yes

**Score 5** a. No
b. No

**TX.2.2.5** Pharmacy services are available when the organization's pharmacy service is closed or not available or when access to medications is limited.

**Intent of TX.2.2.5**

Organizations that prepare, dispense, or store medications deliver consistent quality during all hours of service. To do this, they establish a means of providing pharmacy services when the pharmacy is closed, not available, or access to medications is otherwise limited.

**Additional Requirements for Methadone/LAAM Treatment Programs**

An up-to-date plan for emergency administration of medications is maintained in case the program must be closed temporarily, including how patients will be informed of these emergency arrangements.

Access to designated program staff is provided 24 hours per day, seven days per week, so that patient emergencies may be addressed and dosage levels may be verified.

**Scoring for TX.2.2.5**

a. Does the organization provide for adequate control, accountability, and availability of medications as described in the intent?
b. In methadone/LAAM treatment programs, is there an up-to-date emergency medication administration plan in case of temporary closure?
c. In methadone/LAAM treatment programs, do patients have access to designated program staff 24 hours per day, 7 days per week in case of emergencies and dosage level verification?

**Score 1** a. Yes b. Yes c. Yes
**Score 2** a. With a few minor exceptions
**Score 3** a. Not consistently
**Score 4** a. Rarely

**Score 5** a. No b. No c. No

**TX.2.3.2** Systems are implemented to support self-administration or alternative medication administration systems.

**Intent of TX.2.3.2**
The organization safely manages medications brought into the organization by the individual. Self-administration of prescribed medications addresses drugs brought into the organization by an individual or those ordered by a licensed independent practitioner while the individual is in the organization. An individual's safe self-administration of medication is supported. Individuals permitted to self-administer medications do so only when specifically ordered by the responsible licensed independent practitioner. A clinical staff member supervises self-administration procedures.

**Additional Requirements for Methadone/LAAM Treatment Programs**

**Take-Home Medications**

Programs consider the following criteria in determining patient eligibility for take-home medication:

- Cessation of illicit drug use;
- The results of urine or other toxicological tests assist clinical staff in making informed decisions regarding take-home medication privileges; however, clinical decisions about take-home medications or discharge are not based solely on urine or other toxicology test reports.
- Regularity of program attendance;
- Length of time and level of treatment in methadone/LAAM therapy (patient's ability to responsibly self-medicate);
- Absence of known recent criminal activity (especially drug dealing);
- Absence of serious behavioral problems;
- Absence of abuse of drugs including excessive use of alcohol;
- Other special needs of the patient, such as split dosing, physical health needs, pain treatment;
- Capacity to safely store take-home medication within the patient's home;
- Stability of the patient's home environment and social relationships;
- Patient's work, school, or other daily life activity schedule; and
- Hardship experienced by the patient in traveling to and from the program.

Criteria for determining the number and quantity of take-home (unsupervised) doses per week include the following:

- first 90 days of treatment: maximum of one unsupervised dose per week;
- second 90 days of treatment: maximum of two unsupervised doses per week;
- third 90 days of treatment: maximum of three unsupervised doses per week;

- remainder of first year and second year: maximum of six unsupervised doses per week; and
- third year: maximum of 30 unsupervised doses per month.

One time or temporary (usually not to exceed three days) take-home medication may be approved for documented family or medical emergencies or other exceptional circumstances.

A multidisciplinary team provides recommendations and input for review, while a physician makes the final decision about approving take-home medication.

Decisions should be reviewed periodically, at least every 90 days and more frequently if indicated, and documented in the patient record. The review should consider and evaluate drug testing results and other relevant clinical factors. The physician's conclusions on this review should be noted in the record.

Program policies enable a physician to evaluate a patient's stability and response to take-home medication, and to adjust doses at regular intervals.

Program policies ensure responsible handling and secure storage of take-home medication in childproof containers.

Programs also inform patients of their rights and responsibilities in ensuring the security of opioid medications.

**Example of Implementation for TX.2.3.2**

For methadone/LAAM treatment programs, at a minimum, individual bottles should have the patient's name, dosage, name and address of the treatment program, and a childproof safety cap. The program may choose to use a locked box when patients take home more than one bottle at a time or have children at home.

**Scoring for TX.2.3.2**

a. Does the organization provide for safe self-administration of medications, as described in the intent?
b. In methadone/LAAM treatment programs, is there a take-home medication plan?
c. In methadone/LAAM treatment programs, are the 11 criteria in the intent considered in determining patient eligibility for take-home medications?
d. In methadone/LAAM treatment programs, do criteria for determining the number and quantity of take-home doses include the first 90 days, second 90 days, third 90 days, remainder of first year, and second year, and third year?
e. In methadone/LAAM treatment programs, are there policies for one time or temporary take-home medication?

f. In methadone/LAAM treatment programs, does a multidisciplinary team provide recommendations and input, with a physician making the final decision of approval for take- home medications?
g. In methadone/LAAM treatment programs, are decisions regarding take-home medications reviewed at least every 90 days, or when appropriate?
h. In methadone/LAAM treatment programs, does a physician evaluate patient stability and response to take home medication and adjust doses at regular intervals?
i. In methadone/LAAM treatment programs, are take-home medications stored in childproof containers?
j. In methadone/LAAM treatment programs, are patients informed of their rights and responsibilities in ensuring the security of opioid medications?

| | | |
|---|---|---|
| **Score 1** | a. Yes | b. Yes |
| **Score 2** | a. With a few minor exceptions | |
| **Score 3** | a. Not consistently | |
| **Score 4** | a. Rarely | |
| **Score 5** | a. No | b. No |

***Note:*** *The following set of scoring applies to each of the remaining score questions (c-j).*

| | |
|---|---|
| **Score 1** | Yes |
| **Score 2** | With a few minor exceptions |
| **Score 3** | Not consistently |
| **Score 4** | Rarely |
| **Score 5** | No |

**TX.2.4** Medication's effect on the individual is monitored continuously.

**TX.2.4.1** Effects of medication are assessed based on information maintained in the individual's clinical record and medication profile and observations by staff and the individual.

**Intent of TX.2.4 and TX.2.4.1**
Medication monitoring is a collaborative process that may include input from various disciplines and the individual and family, when appropriate. This information is used to maintain and improve the outcomes of drug therapy while minimizing any drug-related problems or adverse events.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Methadone/LAAM therapy has three desired clinical effects, which are, in ascending importance:

1. Preventing the onset of subjective and/or objective signs of opioid abstinence syndrome for 24 hours or more;
2. Reducing or eliminating the drug hunger or craving routinely experienced by the opioid-addicted individual when not in treatment; and

3. Blocking the effects of any illicitly acquired, self-administered opioids without inducing persistent euphoric or other undesirable effects that are experienced by the patient or noticed by other observers.

Methadone is continued as long as benefit is derived from treatment and the treatment is desired by the patient. Methadone or LAAM maintenance medication doses are sufficient to produce the desired response in the patient for the desired duration of time, with allowance for a margin of effectiveness and safety.

Methadone is a medication: It should not be standard practice to manipulate doses to reinforce positive behavior or to punish negative behavior. However, there are exceptions to this rule. Sometimes the patient's need for acute or emergency medical care may be urgent and may take precedence over the need for a single day's dose at the program.

**Maintenance Therapy**

A documented history and physical examination supports the judgment by the physician that the patient is a suitable candidate for methadone/LAAM therapy.

The initial full day dose of methadone is based on the physician's evaluation of the history and present condition of the patient, with added knowledge of such local conditions as the relative purity of available street drugs.

The usual initial dose of methadone should be from 20-30 milligrams. Reasons for exceeding an initial dose of 30 mg. need to be carefully documented in the clinical chart and should not exceed 40 mg., unless the physician documents in the patients' record that 40 mg. did not suppress opiate abstinence symptoms after a three hour period of observation. Addicted patients abusing diverted medical opioids alone may require a lower initial dose of methadone, and should have the initial dose of methadone based on standard dose conversion tables and their recent amount of opioid intake.

Initial dosing of LAAM and other approved medications should be based on the package insert. Deviations from this must be documented by the physician.

***Note:*** *Clinics providing treatment with LAAM must advise all patients of childbearing potential of the risks of LAAM and make a medical evaluation available to all patients who become pregnant while taking the drug, and have a mechanism to ease the transition from LAAM to methadone.*

Induction and maintenance dosages follow the principles defined in TIP 1, *State Methadone Treatment Guidelines*, with particular attention to steady-state pharmacokinetics with accumulation during the induction process.

The initial methadone dose for a newly admitted pregnant patient and the subsequent induction and maintenance dosing strategy reflect the same effective dosing protocols used for all other patients.

The maintenance dose is individually determined with careful and caring attention to the essential information provided by the patient; the dose should be determined by a physician experienced in addiction treatment and should be adequate to achieve the desired effects for 24 hours or more with allowance for day-to-day fluctuations and elimination patterns.

The total dose of methadone and the interval between doses may require adjustments for patients who have atypical metabolism patterns or are prescribed other concurrent medications which alter rates of methadone metabolism.

Programs maintain patients who become pregnant during treatment on the pre-pregnancy dosage, if effective, and applies the same dosing principles as used with any other non-pregnant patient.

The methadone dose is carefully monitored for pregnant patients, especially during the third trimester when pregnancy induced changes in the rate at which methadone is metabolized or eliminated from the system may necessitate either an increased or split dose.

Treatment programs monitor patient's prescribed take-home medications in a manner that complies with Federal regulations.

**Medical Withdrawal**

Medical withdrawal refers to a medically supervised, gradual reduction or tapering of dose over time to achieve the elimination of tolerance and physical dependence to methadone or LAAM.

Voluntary withdrawal from methadone/LAAM therapy--as distinct from involuntary withdrawal and administrative withdrawal and other types of withdrawal--is initiated only when desired by the rehabilitated patient, in partnership with the physician.

If medical withdrawal is initiated, dosages of methadone or LAAM are reduced at a rate that is well tolerated by the patient and also in accordance with sound medical practices.

For women of childbearing potential, the results of a pregnancy test are reviewed before initiating medical withdrawal of methadone or LAAM.

If a pregnant patient elects to withdraw from methadone, a physician experienced in addiction medicine supervises the withdrawal process, regular fetal assessments as appropriate for

gestational age are part of the withdrawal process, and withdrawal is not initiated before 14 weeks or after 32 weeks gestation.

**Scoring for TX.2.4**

a. Is the medication's effect on individuals continually monitored?
b. In methadone/LAAM treatment programs, does methadone/LAAM therapy produce the desired clinical effects?
c. In methadone/LAAM treatment programs, do the history and physical examination findings support that the patient is a suitable candidate for methadone/LAAM therapy?
d. In methadone/LAAM treatment programs, is the initial full day dose of methadone based on physician evaluation of the history and present condition of the patient, with added knowledge of local conditions?
e. In methadone/LAAM treatment programs, is the initial dose of methadone 20-30 milligrams with documentation explaining if dose is greater than 30 milligrams?
f. In methadone/LAAM treatment programs, is the initial dose of LAAM based on the package insert, with deviations from the insert documented?
g. In methadone/LAAM treatment programs, does the initial methadone dose and the maintenance dose for newly admitted pregnant patients reflect the same dosing protocols used for other patients?
h. In methadone/LAAM treatment programs, is the maintenance dose individually determined by a physician experienced in addiction medicine and is the maintenance dose adequate to achieve the desired effects for 24 hours or more?
i. In methadone/LAAM treatment programs, is the total dose of methadone and the interval between doses adjusted for patients based on their methadone metabolism patterns or rates?
j. In methadone/LAAM treatment programs, are patients who become pregnant during treatment maintained on the pre-pregnancy dosage, if effective and are the same dosing principles applied as used with any other non-pregnant patient?
k. In methadone/LAAM treatment programs, is the methadone dose carefully monitored for pregnant patients?
l. In methadone/LAAM treatment programs, does monitoring of patient prescribed take-home medication comply with Federal Regulations?
m. In methadone/LAAM treatment programs, is voluntary withdrawal from methadone/LAAM therapy initiated only when desired by the rehabilitated patient, in partnership with the physician?
n. In methadone/LAAM treatment programs, when medical withdrawal is initiated, are doses reduced at a rate that is well tolerated by the patient and in accordance with sound medical practices?
o. In methadone/LAAM treatment programs (for women of childbearing potential), are the results of a pregnancy test reviewed before initiating medical withdrawal?
p. In methadone/LAAM treatment programs, if a pregnant patient elects to withdraw from methadone, does a physician experienced in addiction medicine supervise the withdrawal process, are fetal assessments part of the withdrawal process, and is withdrawal not initiated before 14 weeks or after 32 weeks gestation?

**Score 1** a. Yes
**Score 2** a. With a few minor exceptions
**Score 3** a. Not consistently
**Score 4** a. Rarely
**Score 5** a. No

***Note:*** *The following set of scoring applies to each of the remaining score questions (b-p).*

**Score 1** Yes
**Score 2** With a few minor exceptions
**Score 3** Not consistently
**Score 4** Rarely
**Score 5** No

***Education (PF)***

**PF.2.2** *Individualized instruction in the knowledge, skills, or behaviors required to meet ongoing health care needs is provided to individuals and families in ways that are understandable to them. Whenever appropriate, instruction is provided regarding*

**PF.2.2.1** safe and effective use of medication, in accordance with legal requirements and individual needs;

**PF.2.2.2** the safe and effective use of medical equipment or supplies;

**PF.2.2.3** potential drug-food interactions and nutrition intervention or modified diets;

**PF.2.2.4** habilitation or rehabilitation techniques to facilitate adaptation to or functional independence in the environment;

**PF.2.2.5** basic safety;

**PF.2.2.6** pain management as part of treatment;

**PF.2.2.7** access to available community resources; and

**PF.2.2.8** resources available to meet the individual's identified needs.

**Intent of PF.2.2 Through PF.2.2.8**

Once the individual's learning needs are identified and prioritized, the educational process begins. Educational interventions are individualized to meet specific learning needs consistent with organization policies and procedures. Methods of education may include

# formal teaching plans;
# informal teaching opportunities; and
# demonstrations of skill or subject mastery by the individual or family.

Education in the safe and effective use of medication includes instruction in at least the name and description of the medication; the dosage, route of administration, and duration of drug therapy; special directions and precautions for the individual's preparation, self-administration, and use of the medication in the organization or at home, including safeguards against microbial contamination and appropriate compounding and administration techniques; intended use and expected actions of the drug therapy; common severe side effects, adverse effects, drug interactions and therapeutic contraindications, and how to avoid or respond to them; techniques for self-monitoring drug therapy; proper storage and expiration dating; prescription refill information; action in response to a missed dose; proper disposal of unused or expired medications, especially Schedule II drugs; and any other information relevant to the individual's particular needs or drug therapy.

When applicable, individuals or family members are informed of any infection prevention or control precautions to be taken, such as universal or barrier precautions. As appropriate, education services encompass health maintenance, including acquired immunodeficiency syndrome and sex education.

At the time of discharge, individuals in need of continuing care or services get written and verbal instruction about resources available to meet their continuing needs.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Education also includes the following for methadone/LAAM treatment programs:

- basic prenatal instruction for pregnant women (when programs do not provide for prenatal care on-site or by referral) which includes at a minimum, maternal, physical, and dietary care as part of the counseling services;
- education and training for all male and female parenting patients, or patients are referred to appropriate parenting skills services.
- reproductive health education for patients, including appropriate referrals for contraceptive services is provided, if indicated.
- HIV/AIDS, testing procedures, confidentiality, reporting, follow-up care, counseling, safer sex, social responsibilities, and sharing of intravenous equipment.

**Scoring for PF.2.2.5**

a. Do individuals or families receive education about basic safety, when appropriate?

b. In methadone/LAAM treatment programs, does education include basic prenatal instruction for pregnant women which includes at a minimum, maternal, physical, and dietary care?
c. In methadone/LAAM treatment programs, does education include training for all male and female parenting patients?
d. In methadone/LAAM treatment programs, does education include reproductive health and referral for contraceptive services for patients, if indicated?
e. In methadone/LAAM treatment programs, does education include HIV/AIDS, testing procedures, confidentiality, reporting, follow-up care, counseling, safer sex, social responsibilities, and sharing of intravenous equipment?

**Score 1** a. Yes
**Score 2** a. With a few minor exceptions
**Score 3** a. Not consistently
**Score 4** a. Rarely
**Score 5** a. No

***Note:*** *The following set of scoring applies to each of the remaining score questions (b-e).*

**Score 1** Yes
**Score 2** With a few minor exceptions
**Score 3** Not consistently
**Score 4** Rarely
**Score 5** No

***Continuum (CC)***

**CC.1** Within its capability, the organization has a process to provide access to the appropriate level of care, health professionals, programs, and services to meet individuals' assessed needs.

**Intent of CC.1**
Individuals are screened at the point of first contact with the organization. After screening, individuals are matched with the services or programs within the organization that are most appropriate to their needs. The organization's decision to provide a specific service or program is based on its mission and capability to provide the requisite staffing, facilities, and services.

Various processes can be designed to ensure individuals gain access to appropriate care on a timely basis. The organization defines what information should be gathered during the screening to determine admission or referral. (See the "Assessment" chapter of this manual [page xxx].)

**Additional Requirements for Methadone/LAAM Treatment Programs**

The process for providing access to care, health professionals, and services also includes:

- program physician documentation that treatment is medically necessary;
- criteria for admission are based on DSM-IV definition of opioid dependence;
- criteria for behavior supportive of a diagnosis of addiction which include:
  - continuing use of the opiate despite known adverse consequences to self, family, or society;
  - obtaining illicit opiates;
  - using prescribed opiates inappropriately; and
  - one or more attempts at gradual removal of physical dependence on opioids (detoxification) using methadone. This is also called medically supervised withdrawal (MSW). An unsuccessful attempt at MSW is evidenced by uncontrollable drug craving (or actual use) caused by insufficient methadone dose during an admission for detoxification or MSW. There should be no artificial barrier created nor should there be a set amount of time that separates the transfer from an unsuccessful attempt at detoxification or MSW directly into the early phase of methadone/LAAM maintenance treatment.

There may be individuals in special populations who have a history of opioid use but who are not currently physiologically dependent. The absence of physiological dependence should not be an exclusion criteria and admission is clinically justified. This is because individuals in these populations are susceptible to relapse to opioid addiction leading to high-risk behaviors with potentially life-threatening consequences. These populations include the following:

- persons recently released from a penal institution;
- persons recently discharged from a chronic care facility;
- pregnant patients;
- previously treated patients; and
- adolescents.

Priority is given to pregnant women who seek treatment; the reason for denying admission to any pregnant applicant is documented on an intake log.

**Scoring for CC.1**

a. Has the organization established processes for matching individuals' needs with appropriate care on a timely basis?

b. Are these processes implemented?

c. In methadone/LAAM treatment programs, does the process for providing access to care, health professionals, and services include program physician documentation that treatment is medically necessary?

d. In methadone/LAAM treatment programs, does the process for providing access to care, health professionals, and services include criteria for admission which are based on DSM-IV definition of opioid dependence?

e. In methadone/LAAM treatment programs, are the criteria for behavior supportive of a diagnosis of addiction?

f. In methadone/LAAM treatment programs, does the process for providing access to care, health professionals, and services address special populations where the absence of physiological dependence should not be an exclusion criteria and admission is clinically justified?
g. In methadone/LAAM treatment programs, is priority given to pregnant women who seek treatment and is the reason for denial of admission documented when such denial occurs?

| | | |
|---|---|---|
| **Score 1** | a. Yes | b. Yes |
| **Score 2** | a. With a few minor exceptions | b. With a few minor exceptions |
| **Score 3** | a. Not consistently | b. Not consistently |
| **Score 4** | a. Rarely | b. Rarely |
| **Score 5** | a. No | b. No |

***Note:*** *The following set of scoring applies to each of the remaining score questions (c-g).*

| | |
|---|---|
| **Score 1** | Yes |
| **Score 2** | With a few minor exceptions |
| **Score 3** | Not consistently |
| **Score 4** | Rarely |
| **Score 5** | No |

**CC.2.1** Criteria define the information necessary to determine an individual's eligibility for entry to a program or service.

**Intent of CC.2.1**
The organization defines the minimum essential information needed to determine an individual's eligibility for entry to a setting or program. The criteria are based on the specific program or service that can meet or respond to the needs or presenting conditions of the individual. To add clarity, entry criteria also include exclusionary statements that indicate the information needed to initiate referral to another, more appropriate program or organization.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Criteria for determining an individual's eligibility for entry to the program also address the following:

- Patients are generally not admitted to methadone/LAAM therapy to receive opioids only for pain;
- Measures are taken to prevent patients from enrolling in treatment provided by more than one clinic or individual practitioner. These measures are commensurate with the severity of the problem and its documented consequences;
- Methadone/LAAM treatment programs should be encouraged to participate in central registries designed and implemented by the state; and
- Individuals under 18 are required to have had two documented attempts at short-term medically supervised withdrawal (detoxification) or drug-free treatment to be eligible for

maintenance treatment. The program physician shall document in the patient's record that the patient continues to be or is again physiologically dependent on narcotic drugs. No individual under 18 years of age, except an "emancipated minor," may be admitted to a maintenance treatment program unless a parent, legal guardian, or responsible adult completes and signs consent form FDA 2635 "Consent to Methadone Treatment" (also see RI.1.2.2 regarding informed consent).

**Scoring for CC.2.1**

a. Do criteria specify the essential information needed to determine an individual's eligibility for entry to a program or service?

b. Is this information consistently obtained and used in making decisions on admission or acceptance of referrals?

c. In methadone/LAAM treatment programs, do criteria specify the additional four requirements regarding eligibility for entry into the program?

| | | | |
|---|---|---|---|
| **Score 1** | a. Yes | b. Yes | c. Yes |
| **Score 3** | a. Not consistently | b. Not consistently | c. Not consistently |
| **Score 5** | a. No | b. No | c. No |

**CC.3** *As appropriate to the settings of care, the services provided, and the individual's condition, individuals and, when appropriate, families receive enough information to make knowledgeable decisions about care and services. Information provided includes*

**CC.3.2** the hours during which care and services are available.

**Intent of CC.3 Through CC.3.5**

Requirements for entry to settings or services are clearly communicated to individuals and, when appropriate, to their families. They are given enough information about the care or services to make a knowledgeable decision about whether to seek them. Insurance coverage and managed care arrangements are explained as part of this process.

Due to the practices of health insurance and managed health care, insurance reviewers, managed care utilization reviewers, and case-management professionals may contribute to clinical decisions about an individual's treatment (including type of care and the clinical necessity for care). These individuals and their employers may work with the clinician in developing the least restrictive and most cost-sensitive treatment plan.

Individuals and, as appropriate, their families should be aware that treatment may be shortened or modified. The individuals served and clinicians always have the right to appeal any funding decisions regarding treatment (see CC.8).

**Additional Requirements for Methadone/LAAM Treatment Programs**

Services should be provided during hours that meet the needs of the majority of patients, including the hours before and/or after the traditional 8 AM to 5 PM working day, when possible.

**Scoring for CC.3.2**

a. Do individuals and, when appropriate, families receive information about the hours during which care and services are available?

b. In methadone/LAAM treatment programs, are services provided to meet the needs of the patients, including before and/or after the traditional 8 AM to 5 PM hours, when possible?

| | | |
|---|---|---|
| **Score 1** | a. Yes | b. Yes |
| **Score 2** | a. With a few minor exceptions | |
| **Score 3** | a. Not consistently | |
| **Score 4** | a. Rarely | |
| **Score 5** | a. No | b. No |

**CC.4** The organization provides for continuity of care and services over time among the assessment and diagnosis, planning, and treatment phases of the individual's services.

**CC.5** The organization provides for coordination of care and services among health professionals and settings.

**Intent of CC.4 and CC.5**

Processes for assessing, planning for, and meeting individuals' health care needs promote smooth transitions from one level of care to the next. Throughout care, individuals are matched with appropriate resources within the continuum (for example, crisis stabilization units, residential care, supervised housing). Services are coordinated to ensure appropriate continuity of care from the time of entry through assessment, planning, treatment, and discharge. Delivery of services to meet each individual's set of biopsychosocial needs is integrated and responsive to changing needs.

**Additional Requirements for Methadone/LAAM Treatment Programs**

The coordination of services should also include:

- the establishment of agreements and development of procedures to coordinate with agents of the criminal justice system on behalf of the patients, and
- communication and cooperation with the criminal justice system in a way that advocates for continuous treatment of incarcerated methadone/LAAM therapy patients as well as those on probation or parole.

**Scoring for CC.5**

a. Are care and services coordinated among practitioners and settings?

b. In methadone/LAAM treatment programs, are services coordinated with agents of the criminal justice system?

| | | |
|---|---|---|
| **Score 1** | a. Yes | b. Yes |
| **Score 2** | a. With a few minor exceptions | b. With a few minor exceptions |
| **Score 3** | a. Not consistently | b. Not consistently |
| **Score 4** | a. Rarely | b. Rarely |
| **Score 5** | a. No | b. No |

**CC.6** Referral, transfer, or discharge of individuals to other levels of care, health professionals, or settings are based on individuals' assessed needs and the organization's capability to provide needed care.

**Intent of CC.6**

Transfer, referral, or discharge processes address

# shifting responsibility for an individual's care from one clinician, organization, organizational unit or clinical service to another (which could include transferring complete responsibility for the individual and his or her care to others or referring the individual to others, such as one or more agencies or professionals, to provide one or more specific services);
# the reason for transfer, referral, or discharge;
# the conditions under which transfer can occur (for example, the individual is not transferred until the receiving organization has consented to accept the individual and the individual is considered sufficiently stabilized);
# responsibility for the individual during transfer; and
# procedures for internal and external referral.

Referrals can be made through formal affiliations or informal arrangements by placement contacts.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Transfer, referral, or discharge processes also address the establishment and use of linkages with HIV/AIDS treatment programs in the community. These linkages should facilitate systems which continue opioid medication for debilitated patients and transfer care to primary physicians when AIDS becomes the primary health concern.

**Scoring for CC.6**

a. Is there a process, which addresses the issues described in the intent, for transfer, referral, and discharge based on individuals' assessed needs?

b. In methadone/LAAM treatment programs, does the process for transfer, referral, and discharge address linkages with HIV/AIDS treatment programs in the community?

| | | |
|---|---|---|
| **Score 1** | a. Yes | b. Yes |
| **Score 2** | a. With a few minor exceptions | b. With a few minor exceptions |
| **Score 3** | a. Not consistently | b. Not consistently |
| **Score 4** | a. Rarely | b. Rarely |

**Score 5** a. No b. No

**CC.6.1** The discharge process provides for continuing care to meet the individual's assessed needs at the time of discharge.

**Intent of CC.6.1**
For some individuals, effective discharge planning addresses how needs will be met as they move to the next level of care. For other individuals, discharge planning will consist of a clear understanding of how to access services in the future should the need arise. Planning identifies individuals' post-discharge needs (for example, physical, emotional, housekeeping, transportation, social), and helps arrange for services to meet those needs. Some options to meet discharge needs include special education, adult foster care, case management, home health services, hospice care, long term care facilities, ambulatory care, support groups, and rehabilitation facilities.

The discharge-planning process involves, as appropriate, the licensed independent practitioner primarily responsible for care management, other appropriate staff, the individual, and the individual's family or significant other. To facilitate continuity of care after discharge, the individual and, when appropriate, the family and/or significant other are assisted in adapting to the care plan.

**Additional Requirements for Methadone/LAAM Treatment Programs**

**Relapse Prevention**

The discharge planning process also addresses relapse prevention. Continuing care includes:

- procedures that address patient's physical and mental health problems following withdrawal from methadone/LAAM therapy, including the need for counseling and appropriate medication to help with sleep disorders, depression, and other problems;
- provisions for continuing care following the last dose of medication and for re-entry to maintenance treatment if relapse occurs;
- continuation of psychosocial treatment for patients electing to discontinue pharmacotherapy;
- tracking of patients and reinstitution of pharmacotherapy at first sign of relapse or impending relapse, if possible; and
- the provision of an opportunity for patients receiving long-term pharmacotherapy services only to receive psychosocial services again if the need emerges.

**Withdrawal and Discharge for Methadone/LAAM Treatment Programs**

The discharge planning process also addresses withdrawal and discharge procedures.

Since it is not always possible to retain patients for as long as they can benefit from treatment, programs should provide two types of withdrawal procedures: medical/therapeutic and administrative. Medical/therapeutic is a voluntary, patient-initiated withdrawal. Administrative withdrawal is usually involuntary.

Ongoing multidrug abuse is not necessarily a reason for discharge unless the patient refuses recommended, more intensive levels of care. Patients engaging in such multidrug use must be carefully evaluated to determine the most therapeutic course of treatment, in light of the fact that many patients (and communities) continue to benefit from methadone/LAAM therapy even when the patients are not fully abstinent from all drugs of abuse. In addition, the patient's condition and the best clinical judgment of the treatment team must also be taken into account.

**Administrative Withdrawal**

Administrative withdrawal may result from

- nonpayment of fees. Remedies may include referral to a more affordable treatment program. As a last resort, programs provide a humane schedule of withdrawal;
- disruptive conduct or behavior considered to have an adverse effect on the program, staff, or patient population of such gravity to justify the involuntary withdrawal and discharge of a patient despite an extremely poor prognosis. Such behaviors include violence, threat of violence, dealing drugs, repeated loitering, flagrant noncompliance resulting in an observable, negative impact on the program, staff, and other patients; and
- incarceration or other confinement.

**Medical Withdrawal**

Medical withdrawal occurs

- as a voluntary and therapeutic withdrawal agreed upon by staff and patient, or
- in response to the request of the patient over the objections of the physician, counselor, and other staff; that is, Against Medical Advice (AMA).

The following policies and procedures promote successful medical withdrawal whether conducted with or against medical advice:

- Dose reduction occurs at a rate well tolerated by the patient;
- A variety of supportive options are available to improve chances of a successful withdrawal;
- Increased counseling is available prior to discharge; and
- Participants are encouraged to attend a self-help program that is sensitive to the needs of methadone/LAAM therapy patients.

Additional considerations for medical withdrawal AMA are as follows:

- The patient has the right to leave treatment when he/she chooses to do so. The program explains the risks of leaving treatment;

- The physician, in consultation with the patient, determines the schedule for withdrawal from methadone/LAAM therapy;
- In the case of a patient who leaves the program abruptly, the program may readmit the patient within 30 days without a formal reassessment procedure; and
- The program documents the issue that caused the patient to seek discharge, and provides full documentation of steps taken to avoid discharge.

**Example of Implementation for CC.6.1**

When administrative (involuntary) withdrawal occurs in a methadone/LAAM treatment program, it is important to think in terms of "rates" of dose reduction rather than a set number of days for withdrawal. The rate of dose reduction can be based on a percentage of the dose resulting in a variable duration based on the starting dose. A treatment program may use a 20% per day reduction. For example, a patient starting at 180 mg per day will have a 15 day withdrawal and a patient starting at 30 mg per day will have a nine day withdrawal.

When medical (voluntary) withdrawal occurs in methadone treatment programs, a 10% per day dose reduction may be appropriate.

**[Place withdrawal schedule tables here]**

**Scoring for CC.6.1**

a. Is there a process for identifying individuals who need discharge planning?
b. Is discharge planning conducted for those who need continuing care?
c. In methadone/LAAM treatment programs, does the discharge planning process address relapse prevention?
d. In methadone/LAAM treatment programs, does the relapse prevention program address physical and mental health problems following withdrawal from methadone/LAAM therapy?
e. In methadone/LAAM treatment programs, does relapse prevention address provisions for continuing care following the last dose of medications and for re-entry to maintenance treatment if relapse occurs?
f. In methadone/LAAM treatment programs, is psychosocial treatment continued for patients electing to discontinue pharmacotherapy?
g. In methadone/LAAM treatment programs, are patients tracked and pharmacotherapy reinstituted at first sign of relapse or impending relapse, when possible?
h. In methadone/LAAM treatment programs, are opportunities provided for patients receiving long-term pharmacotherapy services only to receive psychosocial services again if the need emerges?
i. In methadone/LAAM treatment programs, does the discharge planning process address administrative withdrawal?
j. In methadone/LAAM treatment programs, does the discharge planning process address medical withdrawal, including AMAs?

| | | | |
|---|---|---|---|
| **Score 1** | a. Yes | b. Yes | c. Yes |
| **Score 2** | a. With a few minor exceptions | b. With a few minor exceptions | |
| **Score 3** | a. Not consistently | b. Not consistently | |
| **Score 4** | a. Rarely | b. Rarely | |
| **Score 5** | a. No | b. No | c. No |

***Note:*** *The following set of scoring applies to each of the remaining score questions (d-j).*

| | |
|---|---|
| **Score 1** | Yes |
| **Score 2** | With a few minor exceptions |
| **Score 3** | Not consistently |
| **Score 4** | Rarely |
| **Score 5** | No |

**Improving Organization Performance (PI)**

**PI.3.1** The organization collects data to monitor its performance.

**Intent for PI.3.1**
Performance monitoring and improvement are data driven. The stability of important processes can provide the organization with information about its performance. Every organization must choose which processes and outcomes (and thus types of data) are important to monitor based on its mission and the scope of care and services provided. The leaders prioritize data collection based on the organization's mission, care and services provided, and populations served (see LD.4.2.2 for priority setting). Data that the organization considers for collection to monitor performance include the following:

- Performance measures related to accreditation and other requirements;
- Risk management;
- Utilization management;
- Quality control;
- Staff opinions and needs;
- Behavior management procedures, if used;
- Outcomes of processes or services;
- Performance measures from acceptable databases;
- Customer demographics and diagnoses;
- Financial data;
- Infection control surveillance and reporting;
- Research data; and
- Performance data identified in various chapters of this manual.

**For all organizations** the following data are required to be collected

• the needs, expectations, and satisfaction of individuals and organizations served; Individuals served and family members can provide information to give an organization insight about process design and functioning. The organization asks them about

- their specific needs and expectations;
- their perceptions of how well the organization meets these needs and expectations**;** and
- how the organization can improve.

The organization can use a number of ways to get input from these groups including perception-of-care surveys, regularly scheduled meetings held with these groups, and focus groups.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Outcomes and processes should be measured and monitored such as

- reducing or eliminating the use of illicit opioids, illicit drugs, and the problematic use of licit drugs;
- reducing or eliminating associated criminal activities;
- reducing behaviors contributing to the spread of infectious diseases; and
- improving quality of life by restoration of physical and mental health and functional status.

**Scoring for PI.3.1**

a. Has the organization identified performance areas for which data will be collected?
b. Has the organization identified satisfaction or perception-of-care data for collection?
c. Have the appropriate detail and frequency of data collection been determined?
d. Are data collected at the frequency and with the detail identified by the organization?
e. In methadone/LAAM treatment programs, are outcomes and processes monitored such as reducing or eliminating the use of illicit opioids, illicit drugs, and the problematic use of licit drugs; reducing or eliminating associated criminal activities; reducing behaviors contributing to the spread of infectious diseases; and improving quality of life?

| | | | | | |
|---|---|---|---|---|---|
| **Score 1** | a. Always | b. Always | c. Always | d. Always | e. Always |
| **Score 2** | a. Usually | b. Usually | c. Usually | d. Usually | e. Usually |
| **Score 3** | a. Sometimes | b. Sometimes | c. Sometimes | d. Sometimes | e. Sometimes |
| **Score 4** | a. Rarely | b. Rarely | c. Rarely | d. Rarely | e. Rarely |
| **Score 5** | a. Never | b. Never | c. Never | d. Never | e. Never |

***Leadership (LD)***

**LD.1.1** A written plan defines a mission, vision, and values for the organization as well as strategic, operational, program-related, and other plans and policies to achieve them.

**Intent of LD.1 Through LD.1.1.1**

Through planning, the organization's leaders create the framework for providing the organization's behavioral health care services. They develop and carry out an effective planning process that produces timely, well-defined goals. The leaders allocate adequate resources and direct activities to achieve these goals.

Planning is a continuous process that consists of

- developing and communicating a mission that describes the organization's purpose and role in the community;
- revising this mission as necessary; assessing the needs of individuals served and other external and internal customers;
- establishing clear long-range, strategic, and operational plans, budgets, resource allocations, and policies;
- eliciting staff input about goals and plans; and
- continuously measuring and assessing performance to ensure that the organization's mission is consistently supported over time.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Procedures are in place to ensure continuity of care for patients in the event of voluntary or involuntary closure of programs or individual practices that include steps for the orderly transfer of patients, records, and assets to other programs or practitioners. Patient records from programs that are closing are secured and maintained in accordance with State and Federal regulations for a specified period of time.

**Scoring for LD.1.1**

a. Does the organization's planning process define a mission, vision, and values?
b. Does the organization's mission statement guide strategic and operational plans, budgets, resource allocations, and policies?
c. In methadone/LAAM treatment programs, are procedures in place to address voluntary or involuntary closure of programs or individual practices?

| | | | |
|---|---|---|---|
| **Score 1** | a. Yes | b. Yes | c. Yes |
| **Score 2** | | b. Plans, budgets, resource allocation, or policies are not consistent with the mission. | |
| **Score 3** | | b. No | |
| **Score 5** | a. No | | c. No |

**LD.1.3.1** Services are designed through the collaboration of the organization’s leaders with, as appropriate, leaders of the various communities served by the organization and other external organizations.

**Intent of LD.1.3.1**

Appropriate members of the organization are involved in service planning. Staff who are most knowledgeable about particular services participate in their planning. When planning services in response to an identified community need, every effort is made to involve relevant community leaders and, when appropriate, other provider organizations.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Community relations also includes

- input from the community on the program's impact in the neighborhood;
- a process for ensuring that the facility's physical appearance is clean and orderly and that the physical setting does not impede pedestrian or traffic flow;
- the establishment of a liaison with the community representatives to share information about the program and community and mutual issues;
- the identification of program personnel who will function as community relations coordinators and define the goals and procedures of the community relations plan;
- the development of program policies and procedures to effectively address or resolve community problems (including patient loitering and medication diversion), and ensuring that program operations do not adversely affect community life;
- the documentation of community relations efforts and community contacts, the evaluation of efforts and contacts over time, and the addressing of outstanding problems or deficiencies; and
- the development of a communication mechanism so that interested parties and potential patients may obtain general information about the program outside regular operating hours.

**Example of Implementation for LD.1.3.1**

A methadone/LAAM treatment program assigns a staff member to act as a community liaison to establish a relationship with local businesses, community members, and the police department. The community liaison asks the businesses, community members and police department to report any suspicious or unusual activities in the surrounding area to the methadone/LAAM program.

**Scoring for LD.1.3.1**

a. Do appropriate leaders and disciplines and relevant community leaders collaborate in service planning, as described in the intent?

b. In methadone/LAAM treatment programs, does the community relations program include the seven areas in the intent?

| | | |
|---|---|---|
| **Score 1** | a. Yes | b. Yes |
| **Score 2** | a. With a few minor exceptions | b. With a few minor exceptions |
| **Score 3** | a. Not consistently | b. Not consistently |
| **Score 4** | a. Rarely | b. Rarely |
| **Score 5** | a. No | b. No |

**LD.1.3.4** Services are available in a timely manner to meet individuals' needs.

**LD.1.3.4.1** Such services are provided either directly or through referral, consultation, or contractual arrangements.

**LD.1.3.4.1.1** External sources of services are approved by appropriate leaders.

**Intent of LD.1.3.4 Through LD.1.3.4.1.1**
As part of the planning process, the organization determines which services it will provide directly to individuals based on their identified needs and in compliance with applicable law and regulation. The organization may decide to provide some services through referral, consultation, or contractual agreement. When services are not provided directly by the organization, a written agreement approved by appropriate leaders describes the services to be provided and requires the source to meet relevant performance expectations of this manual.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Services should be provided, or referrals made, for individuals who have coexisting health and psychosocial issues. Coexisting health and social issues or needs may include:

- medical problems;
- other addiction problems;
- chronic pain disorder;

  ***management of chronic pain includes consultation with a specialist in pain medicine, when possible and appropriate;
- mental health and family problems;

  ***programs should establish a mechanism to evaluate mental health medication jointly with the mental health provider. If possible and indicated, programs may even dispense such medications in conjunction with the daily methadone dose;
- use/abuse of multiple drugs and/or alcohol;
- HIV or other sexually transmitted diseases;
- infectious diseases;
- pregnancy and prenatal care;
- vocational and employment needs; and
- legal services needs.

**When possible, comorbidities are concurrently managed on-site. Coexisting conditions, especially in patients from disenfranchised populations are most effectively treated at a single site.

Treatment programs ensure that every pregnant patient has the opportunity for prenatal care, provided either on-site or by referral to appropriate health care providers. If referred, the treatment program has agreements in place, including informed consent procedures, that ensure reciprocity in the exchange of pertinent clinical information regarding compliance with the recommended course of medical care (see RI.1.2.2 regarding obtaining of informed consent).

**Scoring for LD.1.3.4.1**

a. Do organization plans address the provision of all essential services, either directly or through referral, consultation, or contract?

b. In methadone/LAAM treatment programs, do the services provided directly or through referral, consultation, or contract address coexisting health and social issues?

| | | |
|---|---|---|
| **Score 1** | a. Yes | b. Yes |
| **Score 2** | a. With a few minor exceptions | b. With a few minor exceptions |
| **Score 3** | a. Not consistently | b. Not consistently |
| **Score 4** | a. Rarely | b. Rarely |
| **Score 5** | a. No | b. No |

**LD.1.7** The scope of services provided by each program or service of the organization is defined in writing and approved by the organization's leaders.

**LD.1.7.1** A written plan guides the provision of services in each program and defines the goals and scope of services offered.

**LD.1.7.2** The written plan for services is based on recognized practice standards and guidelines, when available.

**Intent of LD.1.7 Through LD.1.7.2**

Policies for each program or service describe the kinds of care and services provided by staff to individuals served and their families. The provision of care and services reflects the organization's mission and recognizes the rights of individuals served, the interdependence of care delivery, and organizational ethical issues. Policies and procedures are developed and carried out as required by the population(s) served, the scope and complexity of individuals' need for care, and the knowledge and skill level of the staff members who provide the care delivery. At a minimum, policies and procedures describe how the needs of the individuals served are assessed and met. Recognized practice standards and guidelines are used in planning services.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Polices for methadone/LAAM treatment programs address the following:

- HIV-positive patients are offered options to balance methadone/LAAM therapy and HIV/AIDS care and treatment;

- Patients who are dually-diagnosed with addiction and a pain disorder are not prohibited from receiving methadone/LAAM therapy for either maintenance or withdrawal in a program setting if such setting provides expertise or is the only source of treatment. Similarly, addiction patients maintained on methadone/LAAM are not prohibited from receiving needed pain treatment including, when appropriate, adequate doses of opioid analgesics;
- Specific needs of female patients;
- Clinical flexibility in assigning female patients to counselors who are sensitive to and trained to address their individual needs (i.e., domestic violence, sexual abuse).
- Appropriate child care services are made available for male and female patients who are parents;
- Encouragement of breast-feeding during methadone/LAAM therapy unless medically contraindicated, i.e., by the presence of HIV or HTLV I and II infection in the mother.
- Establishment and implementation of policies, including informed consent, to ensure appropriate follow-up primary care of new mothers and well baby care for the infants (see RI.1.2.2 regarding informed consent);
- Pregnant women in methadone/LAAM therapy with concomitant HIV infection are subject to the same policies and procedures established for all HIV-infected patients in treatment and receive the same services and patients with AIDS diagnoses are offered the same treatment opportunities and services, directly or by referral, as AIDS-diagnosed patients who are not pregnant;
- All pregnant patients with concurrent HIV infection are informed that AZT is currently recommended to reduce perinatal transmission and are provided with appropriate referrals and case management for this treatment;
- Treatment in groups organized by special needs (such as gender, sexual minority, seniors, adolescents, Spanish language) is offered; and
- Programs should have dosing policies based on empirical data and individual needs rather than stating inflexible upper dosage limits.

Policies and procedures should be reviewed and recertified at least annually.

**Example of Implementation for LD.1.7.1**

A methadone treatment program provides child care services on-site if space permits or arranges (through a written agreement) for the provision of child care services with a nearby child care program if adequate space is not available for such services.

**Example of Implementation for LD.1.7.2**

Leaders utilize all applicable CSAT Treatment Improvement Protocols (TIPs) in the planning of methadone/LAAM services.

**Scoring for LD.1.7.1**

a. Does the written plan for the provision of services define the goals of the services?
b. Does the written plan for the provision of services define the scope of services provided?
c. In methadone/LAAM treatment programs, do policies address the above intent requirements?
d. In methadone/LAAM treatment programs, are policies and procedures reviewed and recertified at least annually.

| | | | |
|---|---|---|---|
| **Score 1** | a. Yes | b. Yes | c. Yes |
| **Score 2** | | | c. With a few minor exceptions |
| **Score 3** | a. Not consistently | b. Not consistently | c. Not consistently |
| **Score 4** | | | c. Rarely |
| **Score 5** | a. No | b. No | c. No |

| | |
|---|---|
| **Score 1** | d. Yes |
| **Score 2** | |
| **Score 3** | d. Not consistently |
| **Score 4** | |
| **Score 5** | d. No |

**LD.2.18.1** Programs or services are directed by one or more individuals whose qualifications, authority, and responsibilities are defined in writing.

**LD.2.18.1.1** Responsibility for administrative and clinical direction is defined in writing.

**LD.2.18.1.1.1** A qualified professional with appropriate clinical training and experience is responsible for the clinical direction of care and service delivery.

**LD.2.18.1.1.2** When there is more than one director of a single program or service, the responsibilities of each are defined in writing.

**LD.2.18.1.1.3** When an organization is partially or totally organized on a team or unit basis, the written plan for clinical services delineates the roles and responsibilities of team members in meeting the identified clinical needs of individuals served, consistent with the organization's goals and programs.

**Intent of LD.2.18.1 Through LD.2.18.1.1.3**
Programs and services may be directed by a qualified professional with appropriate training and experience or by a qualified licensed independent practitioner who has appropriate clinical privileges. If the director is not a clinician, then another qualified individual is responsible for directing clinical services.

The directors of programs and services also have adequate management skills to effectively direct the programs or services and fulfill their many responsibilities. Some of these responsibilities may be delegated to others in the program, service, or organization. It may be appropriate for the

program or service director to delegate some responsibilities for policies and procedures, technical staffing, equipment and space, quality control programs, safety, or performance improvement activities to others who are more qualified to address them. Nonetheless, the director has ultimate responsibility for the activities in LD.2.1 through LD.2.17.

When there is more than one director of a program or service, the responsibilities of each are defined in writing to facilitate collaboration, cooperation, and resolution of decision-making conflicts.

Treatment roles and responsibilities of team members are consistent with the needs of individuals served and the service's goals and objectives. Assignment of staff roles and responsibilities may vary based on the needs of the organization's age and disability groups.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Programs ensure that persons in positions of authority are professionally and culturally competent (for example, that these persons are able to work effectively with the local community and/or receive input from advisors or committee members in the local community in terms of gender, ethnicity and language or are representative of it).

**Scoring for LD.2.18.1**

a. Are all care delivery services directed by a competent (and as required, licensed) individual whose qualifications, authority, and responsibilities are defined in writing?
b. In methadone/LAAM treatment programs, are staff in positions of authority professionally and culturally competent?

| | | |
|---|---|---|
| **Score 1** | a. Yes | b. Yes |
| **Score 3** | a. Not consistently | b. Not consistently |
| **Score 5** | a. No | b. No |

**Management of the Environment of Care (EC)**

**EC.1** *The organization establishes an environment of care that meets the needs of individuals served, encourages a positive self-image, and respects their human dignity.*

**EC.1.1** Waiting or reception areas are comfortable; their design, location, and furnishings accommodate visitors and individuals served, the anticipated waiting time, the need for privacy and/or support from staff, and the organization's goals.

**EC.1.2** Enough rest rooms are available for the number of individuals served.

**Intent of EC.1 Through EC.1.2**

The buildings and grounds should promote a therapeutic environment that enhances the self-image of individuals served. The physical structure, grounds, and space are adequate to meet the needs of individuals served and their families and contribute to the enhancement of the organization's neighborhood and community.

Available outdoor space is adequate, based on programs offered and the needs, age, and disability of individuals served. Physically challenged people have access to all necessary services and programs in accordance with the Americans with Disabilities Act (ADA); in federally owned and operated facilities, physically challenged people have access to all necessary services and programs in accordance with the Uniform Federal Accessibility Standards (UFAS).

Waiting and reception areas are adequate in size and number and staffed according to the needs of individuals served. Enough rest rooms are available for the persons using the facility. Drinking fountains or water coolers are available and appropriate for the age and disability groups served (for example, children or wheelchair-bound individuals). Only single-use disposable cups are used, if necessary.

**Additional Requirements for Methadone/LAAM Treatment Programs**

The use of physical space, including bathrooms, reflects the special needs of female patients.

**Scoring for EC.1.1 and EC.1.2**

**Note:** *Standards EC.1.1 and EC.1.2 are scored together.*

a. Are all issues described in the standards and intent addressed?
b. In methadone/LAAM treatment programs, does physical space reflect the special needs of female patients?

| | | |
|---|---|---|
| **Score 1** | a. Yes | b. Yes |
| **Score 2** | a. With a few minor exceptions | b. With a few minor exceptions |
| **Score 3** | a. Not consistently | b. Not consistently |
| **Score 4** | a. Rarely | b. Rarely |
| **Score 5** | a. No | b. No |

**EC.2.2** A management plan addresses security.

**Intent of EC.2.2**
A plan describes how the organization establishes and maintains a security management program to protect individuals served, staff, and visitors from harm. The plan provides processes for

a. leaders' designation of staff responsible for developing, implementing, and monitoring the security management plan;
b. addressing security issues concerning individuals served, visitors, staff, and property;

c. reporting and investigating all security incidents involving individuals served, visitors, staff, or property;
d. providing identification, when appropriate, for all staff, individuals served, or visitors,
e. controlling access to sensitive areas, as determined by the organization;
f. an orientation and education program addressing security management;
g. ongoing monitoring of performance regarding actual or potential risks related to one or more of the following:

- Staff knowledge and skills
- Level of staff participation
- Monitoring and inspection activities
- Emergency and incident reporting
- Inspection, preventive maintenance, and testing of equipment;

h. emergency procedures that address security incidents or failures; and
i. evaluating the security management plan annually.

**Additional Requirements for Methadone/LAAM Treatment Programs**

The security management plan should include training for staff to handle physical or verbal threats, acts of violence, inappropriate behavior, or other escalating and potentially dangerous situations, with emphasis on when security guards or police need to be summoned.

**Scoring for EC.2.2**

a. Does the organization meet the performance expectations for security management planning listed in the intent?

b. In methadone/LAAM treatment programs, does the security management plan include training for staff to handle physical or verbal threats, acts of violence, inappropriate behavior, and potentially dangerous situations?

**Score 1** a. Yes
**Score 2** a. One element (a through i) in the intent is not met
**Score 3** a. Two to four elements (a through i) in the intent are not met
**Score 4** a. Five to seven elements (a through i) in the intent are not met
**Score 5** a. Eight or more elements in the intent are not met

**Score 1** b. Yes
**Score 2** b. With a few minor exceptions
**Score 3** b. Not consistently
**Score 4** b. Rarely
**Score 5** b. No

**EC.2.4** A management plan addresses emergency preparedness.

**Intent of EC.2.4**

A plan describes how the organization establishes and maintains an emergency-preparedness management program to ensure effective response to disasters or emergencies affecting the operations of the organization. The plan provides processes for

j. carrying out specific procedures in response to a variety of disasters or emergencies;
k. defining and, when appropriate, integrating the organization's role with communitywide emergency-preparedness efforts;
l. notifying external authorities of emergencies;
m. notifying staff when emergency response measures are initiated;
n. assigning available staff in emergencies to cover all necessary staff positions;
o. managing space and supplies;
p. providing for back-up services if necessary;
q. a back-up communication system in the event of failure during disasters and emergencies;
r. an orientation and education program for staff who participate in the emergency preparedness plan;
s. ongoing monitoring of performance regarding actual or potential risks related to one or more of the following:

- Staff knowledge and skills
- Level of staff participation
- Monitoring and inspection activities
- Emergency and incident reporting
- Inspection, preventive maintenance, and testing of equipment:

t. evaluating the emergency-preparedness management plan annually.

**Additional Requirements for Methadone/LAAM Treatment Programs**

The disaster plan includes links to community agencies and insures emergency dosing.
The program maintains a 24-hour telephone answering capability to respond to facility and patient emergencies. A roster of patients and a log of medication dosages are accessible to the staff person on call for verification purposes.

**Scoring for EC.2.4**

a. Does the organization meet the performance expectations for emergency-preparedness planning listed in the intent?
b. In methadone/LAAM treatment programs, does the disaster plan include links to community agencies and insure emergency dosing?
c. In methadone/LAAM treatment programs, is 24-hour telephone answering capability maintained to respond to emergencies?

**Score 1** a. Yes
**Score 2** a. One element (a through k) in the intent is not met
**Score 3** a. Two to four elements (a through k) in the intent are not met
**Score 4** a. Five to seven elements (a through k) in the intent are not met

**Score 5** a. Eight or more elements in the intent are not met

| | | |
|---|---|---|
| **Score 1** | b. Yes | c. Yes |
| **Score 5** | b. No | c. No |

**Management of Human Resources (HR)**

**HR.2** The organization provides an adequate number of staff members whose qualifications are consistent with job responsibilities.

**Intent of HR.2**
The organization provides an adequate number of staff members with the experience and training needed to serve and fulfill the program and services part of the organization's mission. Program and service leaders compare projected needs to data and information on current staff numbers and qualifications. This analysis can support, if necessary, proposed modifications for each program or service staff allocation.
The organization establishes staff plans based on

# the needs of individuals served, for example, age and disability considerations;
# organization and program goals and objectives;
# the care and services provided; and
# the need to coordinate care and services.

Generally, programs providing intensive treatment to individuals with severe disabilities will have greater staffing needs. However, no specific staffing formulas, quotas, or models are used for determining compliance; rather, each organization establishes its own staffing plan consistent with its needs.

When appropriately qualified clinical staff are not available or needed on a full-time basis, arrangements are made to get enough staff on an attending, continuing, consultative, or part-time basis.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Staff should be on duty who are trained and proficient in CPR, management of opiate overdose, and other techniques, as appropriate.

Staff understand the benefits and the limitations of urine screening and other toxicological testing procedures.

Staff are knowledgeable about current, effective strategies for treating alcohol, cocaine, and other drug abuse.

Appropriately trained, experienced, and qualified substance abuse counselors provide services of the intensity and duration required to meet the individual needs of the patient population. Staffing patterns are determined by the characteristics and needs of a particular patient population. Patient to staff ratios are sufficient to ensure reasonable and prompt access to counselors by patients and to provide the frequency and intensity of counseling services required.

Staff who are responsible for making linkages for the coordination of medical and psychiatric patient care are knowledgeable about pharmacotherapy treatment (i.e., drug interactions, acute withdrawal, and overdose).

**Scoring for HR.2**

a. Are there enough qualified staff to meet care and service needs, as described in the intent?
b. In methadone/LAAM treatment programs, are staff available who are trained and proficient in CPR, management of opiate overdose, and other appropriate techniques?
c. In methadone/LAAM treatment programs, do staff understand the benefits and limitations of urine screening and other toxicological testing?
d. In methadone/LAAM treatment programs, are staff knowledgeable about strategies for treating alcohol, cocaine, and other drug abuse?
e. In methadone/LAAM treatment programs, do appropriate trained and qualified substance abuse counselors provide services to meet patient needs and are counselors sufficient in number to ensure reasonable and prompt access to counseling by patients?
f. In methadone/LAAM treatment programs, are staff responsible for coordinating and linking medical and psychiatric patient care knowledgeable about pharmacotherapy treatment?

**Score 1** a. Yes
**Score 5** a. No

***Note:*** *The following set of scoring applies to each of the remaining score questions (b-f).*

**Score 1** Yes
**Score 3** Not consistently
**Score 5** No

**HR.3.2** An orientation process provides initial training and information.

**Intent of HR.3.2**

Each staff member's capability to perform specified duties is assessed by completing an orientation. The orientation familiarizes staff members with their responsibilities and the work place before beginning care and service delivery and other activities. Orientation may also include training in-service unit practices and use of equipment. Volunteers are oriented to care and service delivery, safety, infection control, and other activities for which competent performance is expected.

**Additional Requirements for Methadone/LAAM Treatment Programs**

All staff should receive initial education specific to the pharmacotherapies to be used and tailored to the patient population served.

**Scoring for HR.3.2**

a. Have staff members completed an orientation designed to promote safe and effective performance of their responsibilities?

b. In methadone/LAAM treatment programs, have staff members received initial education specific to the pharmacotherapies to be used?

| | | |
|---|---|---|
| **Score 1** | a. 100% of staff members | b. 100% of staff members |
| **Score 2** | a. 95% to 99% of staff members | b. 95% to 99% of staff members |
| **Score 3** | a. 90% to 94% of staff members | b. 90% to 94% of staff members |
| **Score 4** | a. 80% to 89% of staff members | b. 80% to 89% of staff members |
| **Score 5** | a. Less than 80% of staff members | b. Less than 80% of staff members |

**HR.3.3** Ongoing education and training maintains and improves staff competence.

**Intent of HR.3.3**

The organization ensures that each staff member participates in education sessions and training to increase knowledge of specific work-related issues. Staff members' competence is periodically assessed by evaluating the ability to fulfill job responsibilities, especially when new procedures or techniques are introduced and updated technology and equipment are used. Programs have in-service education appropriate to the age and developmental needs of individuals served.

Clinical supervision and consultation are available to clinical practitioners and other staff to maintain and enhance their knowledge, skills, and attitudes in providing care and services.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Staff are trained to respond to medical emergencies within the clinic or office environment.

All staff receive intensive training in the specific characteristics and needs of women participating in the program.

An individual annual training program should be implemented.

Staff have resources for problem solving and troubleshooting.

Records are kept of staff training events, including the qualifications of educators, outline of content, description of methods, and attendees.

**Scoring for HR.3.3**

a. Do staff members participate in an ongoing in-service or other education program as described in the intent?

b. In methadone/LAAM treatment programs, are staff trained to respond to medical emergencies?

c. In methadone/LAAM treatment programs, are staff trained in the specific characteristics and needs of women participating in the program?

d. In methadone/LAAM treatment programs, are individual annual training programs implemented?

e. In methadone/LAAM treatment programs, do staff have resources for problem solving and troubleshooting?

f. In methadone/LAAM treatment programs, are records maintained for staff training events?

| | | |
|---|---|---|
| **Score 1** | a. 90% to 100% of staff members | b. 90% to 100% of staff members |
| **Score 2** | a. 75% to 89% of staff members | b. 75% to 89% of staff members |
| **Score 3** | a. 50% to 74% of staff members | b. 50% to 74% of staff members |
| **Score 4** | a. 25% to 49% of staff members | b. 25% to 49% of staff members |
| **Score 5** | a. Less than 25% of staff members | b. Less than 25% of staff members |

| | | |
|---|---|---|
| **Score 1** | c. 90% to 100% of staff members | d. 90% to 100% of staff members |
| **Score 2** | c. 75% to 89% of staff members | d. 75% to 89% of staff members |
| **Score 3** | c. 50% to 74% of staff members | d. 50% to 74% of staff members |
| **Score 4** | c. 25% to 49% of staff members | d. 25% to 49% of staff members |
| **Score 5** | c. Less than 25% of staff members | d. Less than 25% of staff members |

| | | |
|---|---|---|
| **Score 1** | e. Yes | f. Yes |
| **Score 3** | e. Not consistently | f. Not consistently |
| **Score 5** | e. No | f. No |

**Information Management (IM)**

**IM.2** *Information management processes protect the confidentiality, security, and integrity of information.*

**IM.2.1** The organization determines appropriate levels of security and confidentiality of data and information.

**IM.2.2** Data and information can be retrieved quickly and easily without compromising their security and confidentiality.

**IM.2.2.1** A written policy allows clinical records to be removed from the organization's jurisdiction and safekeeping only in accordance with law and regulation.

**IM.2.2.2** Well-defined processes are used to preserve the confidentiality of data and information deemed sensitive or requiring extraordinary means to protect the privacy of the individuals served.

**IM.2.3** The organization effectively safeguards records and information against loss, destruction, tampering, and unauthorized access or use.

**Intent of IM.2 Through IM.2.3**

The organization is responsible for maintaining the security and confidentiality of data and information. The conflict between data access and sharing and data confidentiality is addressed. The organization determines the level of security and confidentiality maintained for different categories of information. Access to each category of information is based on need and defined by job title and function. An effective security and confidentiality process defines

# who has access to information;
# the information to which an individual has access;
# the user's obligation to keep information confidential;
# when release of health information or removal of the clinical record is permitted;
# how information is protected against loss, destruction, unauthorized intrusion or use, corruption, and damage; and
# the process followed when confidentiality and security may have been violated.

**Additional Requirements for Methadone/LAAM Treatment Programs**

The program adheres to all requirements of the federal confidentiality regulations (42 CFR Part 2).

Protection of confidentiality is ensured with the use of locked files.

**Scoring for IM.2.2.2**

a. Has the organization established processes to preserve the confidentiality of data and information deemed sensitive or thought to require extraordinary measures to protect the privacy of individuals served?
b. Are these processes consistently carried out?
c. In methadone/LAAM treatment programs, are the federal confidentiality regulations adhered to?

| | | | |
|---|---|---|---|
| **Score 1** | a. Yes | b. Yes | c. Yes |
| **Score 3** | a. Not consistently | b. Not consistently | c. Not consistently |
| **Score 5** | a. No | b. No | c. No |

**Scoring for IM.2.3**

a. Are records and information protected at all times against loss, destruction, tampering, and unauthorized access or use?
b. In methadone/LAAM treatment programs, is confidentiality ensured with the use of locked files?

| | | |
|---|---|---|
| **Score 1** | a. Yes | b. Yes |
| **Score 3** | a. Not consistently | b. Not consistently |
| **Score 5** | a. No | b. No |

**IM.3.2** The organization collects data in a timely, economical, and efficient manner, with the degree of accuracy, completeness, and discrimination necessary for their intended use.

**Intent of IM.3 Through IM.3.3**
Standardization of definitions and terminology facilitates comparison of data within the organization and with other organizations. When available, the organization uses national and state guidelines for data-set uniformity and connectivity.

Uniform application of accepted data definitions, codes, classifications, and terminology supports data pooling and analysis and provides criteria for decision analysis. Quality control systems are used to monitor data content and ensure that data collection is timely and economical. The health care team collecting and reviewing data is responsible for its accuracy and completeness.

**Additional Requirements for Methadone/LAAM Treatment Programs**

Programs should develop and implement procedures to avoid duplication of information gathering without compromising objectives of multiple agencies.

**Scoring for IM.3.2**
a. Is data collected in a timely, economical, and efficient manner with the degree of accuracy, completeness, and discrimination necessary for their intended use?
b. In methadone/LAAM treatment programs, are procedures developed and implemented to avoid duplication of information gathering without compromising objectives of multiple agencies?

| | | |
|---|---|---|
| **Score 1** | a. Yes | b. Yes |
| **Score 2** | a. With a few minor exceptions | b. With a few minor exceptions |
| **Score 3** | a. Not consistently | b. Not consistently |
| **Score 4** | a. Rarely | b. Rarely |
| **Score 5** | a. No | b. No |

**IM.7.2** The clinical record contains enough information to identify the individual, support the diagnosis, justify the treatment, document the course and results, and facilitate continuity of care among health care providers. Each clinical record contains

**IM.7.2.20** every dose of medication administered and any adverse drug reaction;

**Intent of IM.7 Through IM.7.2.27**
The information management system can recall historical data about specific individuals as well as access data about current encounters. Information management processes enable using individual-specific data and information to

# facilitate care delivery;
# serve as a financial and legal record;
# aid in clinical research;
# support decision making; and
# guide professional and organizational performance improvement.

Individual-specific data and information is produced and used by a diverse group, including administrative staff, support services, and direct care providers. To facilitate consistency and continuity in care delivery, very specific data and information are required, as outlined in the standards. Recording and using individual-specific information is timely, accurate, secure, and confidential.

For individuals receiving partial-hospitalization or outpatient care or services for continuing care, defined as three or more visits, the clinical record includes a list of significant diagnoses, conditions, procedures, drug allergies, and medications. The record's format offers easy access to this information, which is stored in the same location in all records to help care and service providers find it quickly and easily before seeing the individual.

The summary list is current and updated as necessary and contains

# significant known diagnoses and conditions;
# significant known past treatment procedures;
# known adverse and allergic drug reactions; and
# currently and recently used medications.

"Known" refers to information gathered as part of the individual's assessment and treatment. If an individual is seen in more than one service in the organization (each of which maintains a separate clinical record), the summary list in each record indicates that there is information in another record.

**Additional Requirements for Methadone/LAAM Treatment Programs**

There is documented justification for methadone dosages in excess of 100 mg.

**Scoring for IM.7.2**
This standard is scored at IM.7.2.1 through IM.7.2.27.

**Scoring for IM.7.2.1 Through IM.7.2.27**

**Note:** *IM.7.2.25 is not scored. The following set of scoring guidelines applies to each of the remaining standards in this set.*

What percentage of clinical records contains the element(s) specified in the standard and intent?

**Score 1** 100% of those reviewed
**Score 2** 90% to 99% of those reviewed
**Score 3** 75% to 89% of those reviewed
**Score 4** 50% to 74% of those reviewed
**Score 5** Less than 50% of those reviewed

In methadone/LAAM treatment programs, what percentage of clinical records contain documented justification for methadone dosages in excess of 100 mg?

**Score 1** 100% of those reviewed
**Score 2** 90% to 99% of those reviewed
**Score 3** 75% to 89% of those reviewed
**Score 4** 50% to 74% of those reviewed
**Score 5** Less than 50% of those reviewed

**IM.9.1** Knowledge-based information systems, resources, and services meet the organization's information needs.

**Intent of IM.9.1**

The organization assesses its needs for knowledge-based information and develops a plan for managing clinical and management literature, reference information, and research data. Information management systems provide access to knowledge-based information needed in

# clinical and management decision making;
# performance improvement activities;
# continuing education of staff;
# individual and family education; and
# research.

**Scoring for IM.9.1**

Does the plan for management of knowledge-based information provide access to clinical and managerial literature, reference information, and, when appropriate, research data to meet the organization's identified needs?

**Score 1** Yes
**Score 2** With a few minor exceptions
**Score 3** Not consistently
**Score 4** Rarely

**Score 5** No

**Example of Implementation for IM.9.1**

Methadone/LAAM treatment programs must have available for use all applicable CSAT Treatment Improvement Protocols (TIPs).

## Suggested Readings and Other Resources

**Consumer Bill of Rights and Responsibilities**
The Advisory Commission on Consumer Protection and Quality in the Health Care Industry was appointed by President Bill Clinton on March 26, 1997, to "advise the President on changes occurring in the health care system and recommend measures as may be necessary to promote and assure health care quality and value, and protect consumers and workers in the health care system." As part of its work, the President asked the Commission to draft a "consumer bill of rights." The following rights and responsibilities have been drawn up by the Commission and have been made a part of these Guidelines:

**a. Information Disclosure**
Consumers have the right to receive accurate, easily understood information and some require assistance in making informed health care decisions about their health plans, professionals, and facilities.

**b. Choice of Providers and Plans**
Consumers have the right to a choice of health care providers that is sufficient to ensure access to appropriate high-quality health care.

**c. Access to Emergency Services**
Consumers have the right to access emergency health care services when and where the need arises. Health plans should provide payment when a consumer presents to an emergency department with acute symptoms of sufficient severity--including severe pain--such that a "prudent layperson" could reasonably expect the absence of medical attention to result in placing that consumer's health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

**d. Participation in Treatment Decisions**
Consumers have the right and responsibility to fully participate in all decisions related to their health care. Consumers who are unable to fully participate in treatment decisions have the right to be represented by parents, guardians, family members, or other conservators.

**e. Respect and Nondiscrimination**
Consumers have the right to considerate, respectful care from all members of the health care system at all times and under all circumstances. An environment of mutual respect is essential to maintain a quality health care system.

Consumers must not be discriminated against in the delivery of health care services consistent with the benefits covered in their policy or as required by law based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

Consumers who are eligible for coverage under the terms and conditions of a health plan or program or as required by law must not be discriminated against in marketing and enrollment practices based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

**f. Confidentiality of Health Information**

Consumers have the right to communicate with health care providers in confidence and to have the confidentiality of their individually identifiable health care information protected. Consumers also have the right to review and copy their own medical records and request amendments to their records.

**g. Complaints and Appeals**

All consumers have the right to a fair and efficient process for resolving differences with their health plans, health care providers, and the institutions that serve them, including a rigorous system of internal review and an independent system of external review.

**h. Consumer Responsibilities**

In a health care system that protects consumers' rights, it is reasonable to expect and encourage consumers to assume reasonable responsibilities. Greater individual involvement by consumers in their care increases the likelihood of achieving the best outcomes and helps support a quality improvement, cost-conscious environment.

**Internet Resources**

- http://home.swbell.net/jtpayte/
- www.atforum.com/index.html

**Additional Resources**

1. Center for Substance Abuse Treatment
Office of Pharmacologic and Alternative Therapies
5600 Fishers Lane
Rockwall II
Rockville, Maryland 20857
301/443-7745
www.samhsa.gov/csat/csat.htm

2. Joint Commission on the Accreditation of Healthcare Organizations
One Renaissance Blvd.
Oakbrook Terrace, IL 60181
Department of Standards
630/792-5900
www.jcaho.org

3. Sharon Dow, Project Director
JCAHO Opioid Accreditation Project
410/772-9391
fax 410/992-5883
E-mail: srrdow@ibm.net

Office of Management and Budget *0930-0194*
*Expiration Date: November 30, 2001*